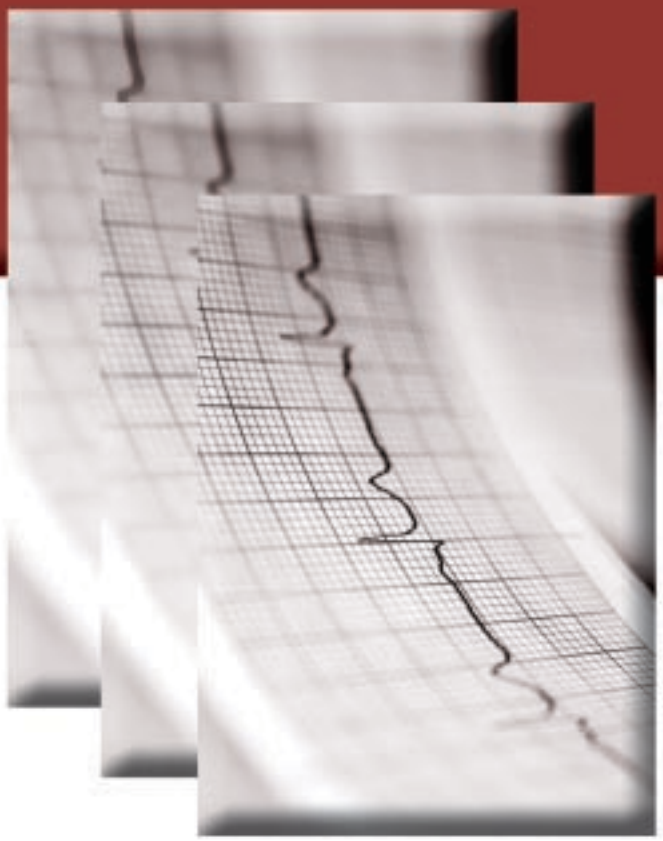
MARYLAND
HEALTH CARE
COMMISSION

Advisory Committee on Outcome Assessment in Cardiovascular Care



Interim Report

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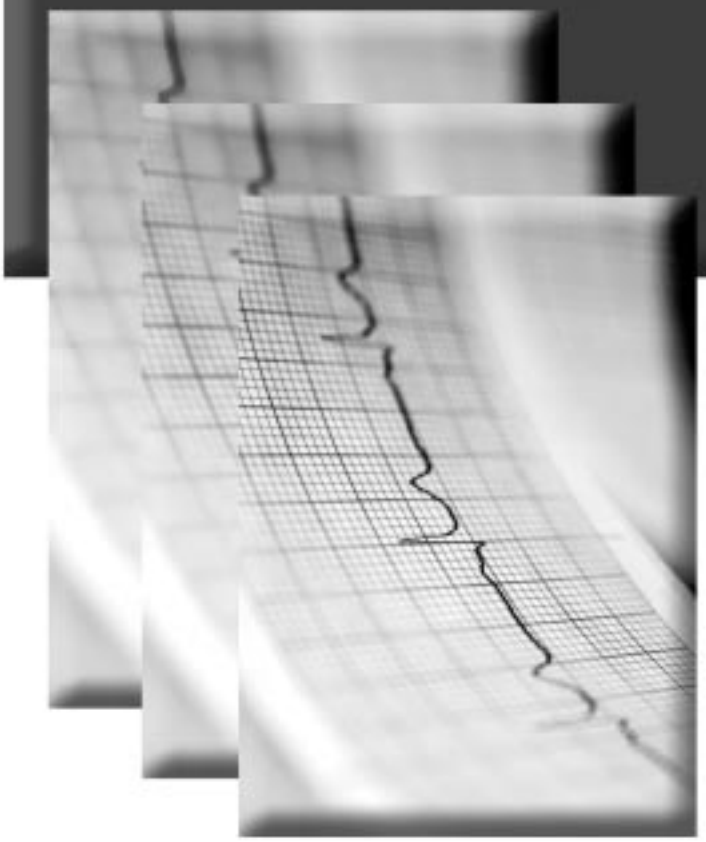


Interim Report

October 2002

Table of Contents

Executive Summary

The updated Maryland State Health Plan chapter, COMAR 10.24.17, governing cardiac surgery and therapeutic catheterization services adopted by the Maryland Health Care Commission became effective in May 2001. In preparing this plan, the Commission recognized the need to establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to promote the development of a Maryland model for continuous quality improvement. In early 2002, the Commission took steps to organize and appoint this Advisory Committee. The Advisory Committee's *Interim Report* to the Commission, the first of two required reports, summarizes activities from March 2002 to September 2002.

The purpose of the Advisory Committee on Outcome Assessment in Cardiovascular Care is to study and develop recommendations to the Commission on establishing an on-going, statewide quality improvement program in cardiovascular care. The goals of this effort are to identify baseline indicators to measure current performance, design an approach for continuous quality improvement, and evaluate options for funding a statewide quality improvement effort. In addition to targeting performance improvement for care currently provided, the Commission wanted to better understand how the organization of cardiac services impacts quality of care and access considerations.

In order to get broad participation in the process, and to focus available expertise in specific areas, the Commission structured the Advisory Committee to include a Steering Committee and four subcommittees. Steering Committee members were appointed by Donald E. Wilson, M.D., Chairman of the Maryland Health Care Commission, after considering nominations received from a wide range of organizations, including hospitals, state and national professional associations, state government, and health care policy research organizations.

STEERING COMMITTEE

James Scheuer, M.D., Professor of Medicine and University Chairman Emeritus at the Albert Einstein College of Medicine/Montefiore Medical Center in New York, chairs the Steering Committee. The Steering Committee is composed of 17 members with expertise in the organization, delivery, and financing of cardiovascular care, including the disciplines of cardiology, cardiac surgery, health services research, emergency medical services, and health care administration. Georges Benjamin, M.D., Secretary of the State of Maryland Department of Health and Mental Hygiene is an ex-officio member of the Steering Committee. Representatives include Maryland providers of specialized cardiac care services as well as representatives with regional and national expertise in the collection and/or analysis of data to support policy development in the area of specialized cardiac care services. The Steering Committee held three meetings between March and September 2002.

- At the first meeting on March 4, 2002, the Steering Committee reviewed its charge, structure, and timetable. Donald E. Wilson, M.D., Chairman of the Maryland Health Care Commission, welcomed Steering Committee members and outlined the goals of the Commission in establishing the Advisory Committee. The Steering Committee approved the establishment of four subcommittees to assist in addressing its charge:

Quality Measurement and Data Reporting; Interventional Cardiology; Long Term Issues; and Inter-Hospital Transport.

- Kenneth I. Shine, M.D., President of the Institute of Medicine (IOM), National Academy of Sciences, and Professor of Medicine Emeritus at the University of California, Los Angeles (UCLA) School of Medicine, spoke at the April 17, 2002 meeting of the Steering Committee. Dr. Shine currently serves as Chairman of the New York State Cardiac Advisory Committee. The New York State Cardiac Advisory Committee has been in existence for more than 25 years and started as a certificate of need (CON) committee. Dr. Shine was appointed Chair in 1994. An expert from outside the State of New York chairs the New York State Cardiac Advisory Committee, with another four to five members also from out of state. Utilizing expertise from outside minimizes internal conflicts of interest as new programs and policies are established. According to Dr. Shine, a key element of success for the New York program was an alliance with Edward L. Hannan, Ph.D., Professor at the University at Albany who assisted with statistical analysis and risk adjustment, forming the template for meaningful analysis in reporting data.

- A third meeting of the Steering Committee was held on June 12, 2002. James L. Field, DBA, Director, Cardiovascular Roundtable, Advisory Board Company in Washington, D.C., briefed the Steering Committee on future trends in cardiovascular services. Dr. Field, also a member of the Steering Committee, said that the industry is in turmoil for a number of reasons: drug-eluting stents; primary angioplasty in hospitals without on-site open heart surgery (OHS); declining OHS volumes overall; pacing or cardiac resynchronization therapy; large number of new OHS programs; and a shortage of cardiologists. Drug-eluting stents have the prospect of leading to an increasing transition of cardiology cases from the operating room to the catheterization lab, with less morbidity and time spent in the hospital. According to Dr. Field, providers are increasingly demanding the capability to perform primary angioplasty due to the widely published results of the Cardiovascular Patient Outcomes Research Team (C-PORT) project. While the overall number of cardiac procedures is increasing, there is a flat or declining curve for OHS volume, especially coronary artery bypass graft (CABG) procedures.

QUALITY MEASUREMENT AND DATA REPORTING SUBCOMMITTEE

Maryland has long recognized the value of reliable health data and has a strong commitment to collecting and using data to support health policy development. Data are required to measure performance, understand underlying components of care that contribute to differences in outcomes, and develop strategies for on-going quality improvement. The Subcommittee on Quality Measurement and Data Reporting is studying and making recommendations to the Steering Committee on issues related to the approach, structure, content, and funding of a Maryland cardiovascular quality improvement program and database.

The Subcommittee includes 17 members representing the disciplines of cardiac surgery, cardiology, outcomes research, biostatistics, clinical data management, and quality assurance.

Luis Mispireta, M.D, Chief of the Division of Cardiac Surgery at Union Memorial Hospital in Baltimore, Maryland, chairs the Quality Measurement and Data Reporting Subcommittee.

- The Quality Measurement and Data Reporting Subcommittee held its first meeting on June 6, 2002. At that meeting, members discussed the charge to the subcommittee from the Steering Committee and received resource materials providing overviews of several national and state quality improvement programs, including Society for Thoracic Surgery (STS) Adult Cardiac Surgery national database, the Northern New England Cardiovascular Disease Study Group, and state-level outcomes measurement and reporting systems from New York and Pennsylvania. Following preliminary discussion, it was the consensus of the subcommittee to focus initial efforts on cardiac surgery and hospital-based interventional cardiology procedures.

- At its second meeting on July 31st, the subcommittee discussed a draft survey to collect information about Maryland hospital cardiac care data systems, and a draft outline of the subcommittee's report. Luis Mispireta, M.D. reported on efforts to develop a consensus among the directors of the cardiac surgery programs in Maryland concerning the most effective and appropriate database for improving outcomes, and the best means of implementing statewide data collection and analysis. At its July 31st meeting, the subcommittee approved the creation of a work group to examine further the data consortium model. The Cardiac Surgery Data Work Group met on September 19th to hear a presentation on issues regarding the confidentiality and public release and issuance of quality improvement data.

- The subcommittee heard presentations on the National Cardiovascular Data Registry of the American College of Cardiology (ACC-NCDR), and the National Adult Cardiac Surgery Data Base and Outcomes Program of the STS at its September 17, 2002 meeting. Dr. Eric Peterson of the Duke Research Institute, which manages data collection activities for the STS database, briefed the subcommittee on the design, organization, and management of the data elements collected in the National Adult Cardiac Surgery Data Base and Outcomes Program. He noted that several states are moving to mandate the participation in the STS survey by their cardiac surgery programs. Dr. Ralph Brindis also briefed the subcommittee on the ACC-NCDR at the September 17, 2002 meeting. He reviewed the evolution of the ACC-NCDR and discussed how the performance and outcome measures collected offer valuable data for quality improvement and policy development.

INTERVENTIONAL CARDIOLOGY SUBCOMMITTEE

Maryland hospitals performed almost 11,000 coronary angioplasty cases in 2001. The evolving use of coronary angioplasty in treating patients with coronary heart disease raises a number of important health policy issues. Among those issues is whether there is sufficient evidence to warrant changing current state health policy to permit hospitals with cardiac catheterization facilities to perform limited angioplasty procedures (i.e., primary angioplasty). With on-going technical improvements in coronary angioplasty procedures, it is also important to review policies governing the requirement for on-site cardiac surgical backup for elective

angioplasty cases. The Subcommittee on Interventional Cardiology is conducting a detailed review of the results of the C-PORT project, the American College of Cardiology/American Heart Association (ACC/AHA) guidelines, and other relevant research and developing recommendations to the Steering Committee on the characteristics of hospitals that should perform primary angioplasty. In addition, the subcommittee is reviewing the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services.

The 26-member Subcommittee on Interventional Cardiology is chaired by David O. Williams, M.D. Dr. Williams is Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. He served on the ACC/AHA Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty.

- The Interventional Cardiology Subcommittee held its first meeting on September 4, 2002, at which the members discussed the charge, structure, and timetable of the subcommittee, and a proposed work plan and process. The subcommittee approved the preparation of a "state of the evidence" paper as part of its process of reviewing policies governing primary and elective angioplasty. This paper will document medical research to date on the questions posed in the charge to the subcommittee regarding both primary and elective angioplasty services. In addition, the subcommittee identified other types of data that will be required to complete its analysis, including information of the volume of acute myocardial infarction (AMI) patients, data on travel times and distances between Maryland acute care hospitals, availability of interventional cardiologists and other required staff, and information on how other states are addressing health policy in this area.

LONG TERM ISSUES SUBCOMMITTEE

One of the key issues in planning for the system of specialized cardiac care services is the assessment of the likely impact of trends that will shape the future health care environment. Those trends include advances in understanding how to prevent heart disease, how to prevent a heart attack, the management and treatment of clinical and sub-clinical heart disease. While a variety of factors have contributed to the declines experienced in heart disease mortality rates, the increased emphasis on and recognition of the importance of healthier lifestyles has clearly played an important role. Despite this encouraging trend, it is likely that heart disease will remain a leading cause of death and disability for the foreseeable future. The Subcommittee on Long Term Issues will identify topics for additional study and develop proposals to further evaluate key policy issues. The subcommittee is also considering the feasibility of developing programs that address other issues in cardiovascular health and disease, including racial and ethnic disparities in cardiac services, primary and secondary prevention (including treatment of patients with diabetes and/or hypertension), risk factor detection and treatment, early identification and treatment of heart attacks, and treatment of patients after ischemic events.

Steering Committee member Eugene R. Passamani, M.D, chairs the Subcommittee on Long Term Issues. Dr. Passamani is currently Director for Cardiology and Medical Education at Suburban Hospital in Bethesda, Maryland. Effective January 2000, Dr. Passamani was elected to the Corporate Office of Vice President, Quality. The 18-member Subcommittee on Long Term

Issues includes members with expertise in cardiology, cardiac surgery, emergency medical services, public health, nursing, health education, and cardiac rehabilitation.

- The Long Term Issues Subcommittee held its initial meeting on June 5, 2002. At that meeting, the subcommittee discussed its charge, structure, and timetable. In addition, the subcommittee had background briefings on three major topics: Healthy Maryland 2010 Project; the problem of heart failure in the United States; and a conceptual overview of a Prospective Heart Failure Patient Outcomes Clinical Trial study. Jeanette Jenkins, Director of the Office of Health Policy in the Community Health Administration of the Department of Health and Mental Hygiene briefed the subcommittee on the goals of the Healthy Maryland 2010 Project with respect to Cardiovascular Disease. Edward Kasper, M.D., Associate Professor of Medicine, Director, Cardiomyopathy and Heart Transplant Service, Johns Hopkins School of Medicine, presented a profile of the compelling problem of heart failure in the United States. A third background briefing at the June 6, 2002 Long Term Issues Subcommittee meeting was presented by Thomas Aversano, M.D., a cardiologist at the Johns Hopkins School of Medicine. Dr. Aversano presented information concerning his concept for a prospective, randomized comparison of usual care with multidisciplinary disease management for heart failure patients.

- The second meeting of the Long Term Issues Subcommittee was held on July 25, 2002. The subcommittee discussed recommendations regarding potential areas of focus for the subcommittee and a draft outline of the subcommittee's report. Focus areas recommended by subcommittee members for further discussion included: encouraging Maryland employers to cover the cost of health/fitness programs; development of a comprehensive approach to cardiovascular disease control to decrease the number of Marylanders who develop and progress to end-stage chronic heart disease; focusing on detection, control, and prevention of hypertension and obesity; education and research about the benefits of early defibrillation; educating physicians about the importance of using comparable generic drugs to contain health care costs; and, aggressive primary and secondary prevention strategies.

INTER-HOSPITAL TRANSPORT SUBCOMMITTEE

The ability to transfer patients from one hospital to another is an important component of the system of care for treating cardiac patients. While many transports that occur between hospitals are for non-emergent reasons, in the area of cardiac care there are patients that require rapid transfer. Although the overall number of cardiac patients requiring rapid inter-hospital transport is comparatively small, some will potentially be eligible for primary angioplasty. For these patients, available data indicate that the effectiveness of the angioplasty intervention is directly related to the time between onset of the acute myocardial infarction and the initiation of the intervention. This factor, combined with the benefits of a system that promotes higher volume cardiac care programs, suggests that access to timely inter-hospital transport is of critical importance. With the growing acceptance and use of primary angioplasty to treat AMI, inter-hospital transport is an important component in planning an optimal system of cardiac care in Maryland. The Subcommittee on Inter-Hospital Transport is studying and developing

recommendations to the Steering Committee on strategies for improving the transport of cardiac patients between hospitals.

Steering Committee member Jeffrey D. Jones, M.D., chairs the Subcommittee on Inter-Hospital Transport. Since 1994, Dr. Jones has been a cardiologist on the staff of Washington County Hospital in Hagerstown, Maryland. He currently practices with Hagerstown Heart, P.A. The 17-member Subcommittee on Inter-Hospital Transport includes members with expertise in cardiology, cardiac surgery, emergency medical services, critical care nursing, and air and ground medical transport systems. In addition to representatives from major providers of cardiac services throughout Maryland, the subcommittee includes experts from the adjacent jurisdictions of Washington, D.C. and Virginia.

- The Inter-Hospital Transport Subcommittee held its first meeting on August 22nd. The subcommittee discussed its charge, structure, and timetable. Cheryl Y. Bowen, M.S., M.A., R.N., Director of Commercial Ambulance Licensing and Regulation for the Maryland Institute for Emergency Medical Services Systems, gave a presentation on the Maryland Neonatal Intensive Care Transport System. The subcommittee also heard information about the development of a private inter-hospital transport system by three Baltimore City/Baltimore County area hospitals that provide cardiac surgery and interventional cardiology services.

Introduction

Background

In Maryland and in the United States as a whole, heart disease is the leading cause of death. During 2000, diseases of the heart claimed about 12,000 lives and accounted for almost one-third of all deaths in Maryland. Over the past several decades, mortality due to diseases of the heart has declined dramatically in Maryland as well as in the United States. Although the complexity of heart disease makes it difficult to determine the precise reasons for the decline in mortality, it is likely that increased emphasis on prevention and improvements in medical care, particularly for patients with acute myocardial infarction (AMI) have contributed to the reduction.

Over the next decade, the baby boom generation will contribute to substantial increases in the older population most at risk for developing heart disease. While awareness of the importance of healthier lifestyles can be expected to moderate future utilization increases, for some patients the impact of minimizing adverse risk factors will be to delay the onset rather than to prevent the development of heart disease. In addition, more people are surviving heart attacks. Reduced mortality from heart attacks has resulted in an increased incidence of congestive heart failure (CHF) in the older patient population. This demographic shift combined with continuing advances in the treatment of heart disease suggests the need to ensure that public policy effectively addresses quality of care, access, and cost issues involving specialized cardiac care services.

To guide public policy governing specialized cardiac care services, the Maryland Health Care Commission prepares a State Health Plan that contains planning policies, a need projection for open heart surgery services, and criteria and standards for reviewing certificate of need (CON) applications. Under Maryland health planning law, the establishment of new open heart surgery and therapeutic catheterization programs requires CON approval. The updated Maryland State Health Plan chapter, COMAR 10.24.17, governing cardiac surgery and therapeutic catheterization services adopted by the Commission became effective in May 2001. In developing this plan, the Commission recognized the need to establish an Advisory Committee on Outcome Assessment in Cardiovascular Care to promote the development of a Maryland model for continuous quality improvement. In early 2002, the Commission took steps to organize and appoint this Advisory Committee.

Interim Report

In establishing the Advisory Committee on Outcome Assessment in Cardiovascular Care, the Maryland Health Care Commission requested two reports. This *Interim Report*, which summarizes the activities of the Advisory Committee from March 2002 to September 2002, is the first of the two required reports. The report is organized in two major sections. Following this Introduction is an overview of the Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care. This section of the *Interim Report* describes the organizational structure of the Advisory Committee and composition of the Steering Committee. The second major section of the *Interim Report* discusses the activities of the four subcommittees appointed to assist the Steering Committee: Quality Measurement and Data Reporting; Interventional Cardiology; Long Term Issues; and Inter-Hospital Transport. For each subcommittee, this section of the report provides background information, a list of subcommittee members, a brief biography of the chairman, and an overview of accomplishments to date. The appendices to the *Interim Report* include summary minutes of the Steering Committee and subcommittee meetings held from March-September 2002.

Advisory Committee on Outcome Assessment in Cardiovascular Care

Purpose of the Advisory Committee

The purpose of the Advisory Committee on Outcome Assessment in Cardiovascular Care is to study and develop recommendations to the Maryland Health Care Commission on establishing an on-going, statewide quality improvement program in cardiovascular care. The goals of this effort are to identify baseline indicators to measure current performance, design an approach for continuous quality improvement, and evaluate options for funding a statewide quality improvement effort. In addition to targeting performance improvement for care currently provided, the Commission is interested in better understanding how the organization of cardiac services impacts quality of care and access considerations. Key tasks involved in this project are outlined below:

- Identify quality measures and risk adjustment methods and develop recommendations on the structure and content of a Maryland Cardiovascular Care Data Reporting System designed to support outcome assessment;
- Study available models for quality improvement in cardiovascular care, focusing initially on cardiac surgery and coronary angioplasty services, and develop recommendations on the appropriate governance, organizational structure, staffing, and funding for an on-going outcome assessment process for cardiovascular care in Maryland;
- Develop a research agenda to advance the understanding of how cardiac care services should be organized to improve outcomes, including, but not limited to, developing an evidence-based approach to reviewing policies governing the location of primary and elective angioplasty services; and
- Identify strategies for developing a statewide inter-hospital transport system for specialized cardiac care services and recommend actions that public and private sector organizations should take to implement an inter-hospital transport system.

Organizational Structure

In early 2002, the Commission took steps to organize and appoint the Advisory Committee on Outcome Assessment in Cardiovascular Care. In order to get broad participation in the process, and to focus available expertise in specific areas, the Commission structured the Advisory Committee to include a Steering Committee and four subcommittees (refer to Figure 1). Steering Committee members were appointed by Donald E. Wilson, M.D., Chairman of the Maryland Health Care Commission, after considering nominations received from a wide range of organizations, including hospitals, state and national professional associations, state government, and health care policy research organizations. The Steering Committee reports directly to the Commission and is responsible for preparing this Interim Report. At the conclusion of the Advisory Committee's work, the Steering Committee will submit a final report to the Commission summarizing its findings and recommendations.

The subcommittees report to the Steering Committee. Each subcommittee includes members from the Steering Committee as well as other interested individuals. Members of the Steering Committee have been appointed to chair each subcommittee. The Commission sought participants from a wide range of organizations, including the Maryland Department of Health and Mental Hygiene, the Maryland Institute for Emergency Medical Services Systems, Maryland acute care hospitals, and state and national professional associations, in appointing subcommittee members. The four subcommittees established to assist the Steering Committee include:

- *Subcommittee on Quality Measurement and Data Reporting*

This subcommittee is studying available models for quality improvement in cardiovascular care and will develop recommendations to the Steering Committee on the approach that should be used in Maryland. As part of this work, the subcommittee is identifying quality measures, risk adjustment methods, the types of data that should be collected on cardiovascular services, and the appropriate method for data collection.

- *Subcommittee on Interventional Cardiology*

This subcommittee is responsible for conducting a detailed review of the results of the Cardiovascular Patient Outcomes Research Team (C-PORT) project and developing recommendations on the types of hospitals that should perform primary angioplasty. In addition, the subcommittee is reviewing the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services.

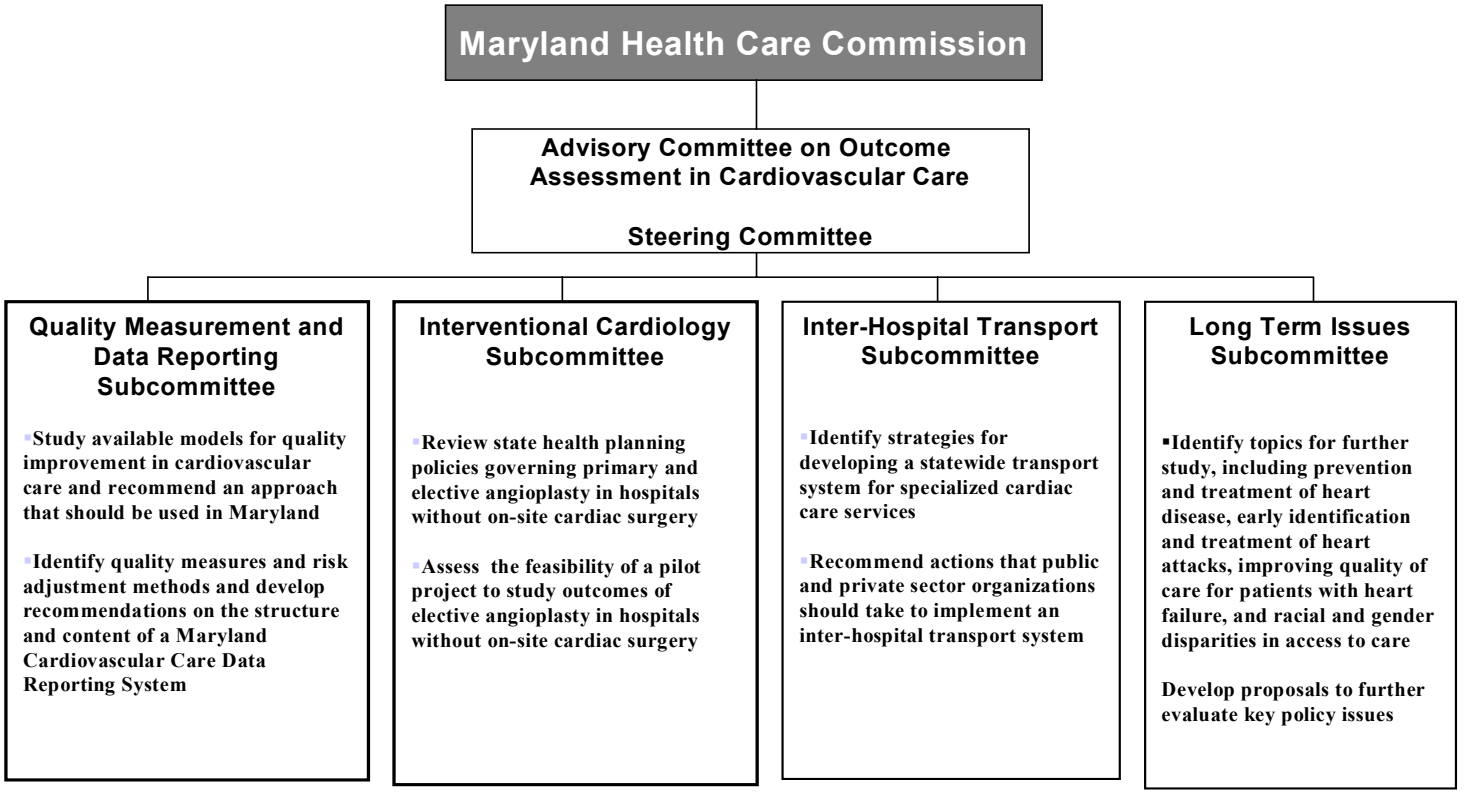
- *Subcommittee on Long Term Issues*

The focus of this subcommittee is on identifying topics for further study, developing proposals to further evaluate key policy issues, and developing a long-range, evidence-based approach for assessing the impact of changes in cardiovascular services. This subcommittee will consider the feasibility and advisability of developing programs that deal with the other issues in cardiovascular health and disease, such as screening, primary and secondary prevention, hypertension, and diabetes care.

- *Subcommittee on Inter-Hospital Transport*

The Subcommittee on Inter-Hospital Transport is studying strategies for improving the transport of cardiac patients between hospitals. The subcommittee is identifying potential strategies for developing a statewide inter-hospital transport system for specialized cardiac care services and recommending actions that public and private sector organizations should take to implement an inter-hospital transport system.

Figure 1 **Organizational Structure: Advisory Committee on Outcome Assessment in Cardiovascular Care**



Steering Committee Composition

The Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care is composed of 17 members with expertise in the organization, delivery, and financing of cardiovascular care, including the disciplines of cardiology, cardiac surgery, health services research, emergency medical services, and health care administration (see Figure 2). Georges Benjamin, M.D., Secretary for the State of Maryland for Health and Mental Hygiene is an ex-officio member of the Steering Committee. Representatives include Maryland providers of specialized cardiac care services as well as representatives with regional and national expertise in the collection and/or analysis of data to support policy development in the area of specialized cardiac care services.

Brief Biography: Steering Committee Chairman

James Scheuer, M.D., Professor of Medicine and University Chairman Emeritus at the Albert Einstein College of Medicine/Montefiore Medical Center in New York, Chairs the Steering Committee. Dr. Scheuer received his medical degree from Yale University Medical School. He served his internship at Bellevue Hospital in New York and his residency at Mount Sinai Hospital, also in New York. Dr. Scheuer trained as a National Institutes of Health postdoctoral fellow at New York Hospital, Cornell Medical Center. He is the past president of the New York Cardiological Society and has served on the editorial boards of many medical journals, including *Cardiology*, *Circulation Research*, *Circulation*, and the *American Journal of Cardiology.*

Accomplishments

The Steering Committee held three meetings between March and September 2002. (Summary minutes of the Steering Committee meetings are provided in Appendix A-2.) At its first meeting on March 4, 2002, the Steering Committee charge, structure and timetable were reviewed. Donald E. Wilson, M.D., Chairman of the Maryland Health Care Commission, welcomed Steering Committee members and outlined the goals of the Commission in establishing the Advisory Committee. The Steering Committee approved the establishment of four subcommittees to assist in addressing its charge: Quality Measurement and Data Reporting; Interventional Cardiology; Long Term Issues; and Inter-Hospital Transport. In addition, the Steering Committee began discussing a number of issues related to developing a Maryland Cardiovascular Quality Improvement (QI) Model, including:

- Where should cardiovascular quality improvement be focused (e.g., prevention versus medical-surgical procedures)?
- What are the elements of quality improvement (e.g., structure, process, and outcome)?
- What should be the terms of participation (e.g., voluntary versus mandatory)?
- Who should sponsor the quality improvement effort (e.g., providers, partnerships, State)?
- How should quality improvement data be reported (e.g., share with peers or public reporting)?

- Who will pay for quality improvement (e.g., providers, partnership, State)?

Kenneth I. Shine, M.D., President of the Institute of Medicine (IOM), National Academy of Sciences, and Professor of Medicine Emeritus at the University of California, Los Angeles (UCLA) School of Medicine, spoke at the April 17, 2002 meeting of the Steering Committee. Dr. Shine currently serves as Chairman of the New York State Cardiac Advisory Committee.

Dr. Shine prefaced his presentation on the experience in New York regarding the issues, pros and cons related to implementing a Cardiovascular QI Model by referring to a letter addressed by Dr. Shine to a California State Senator (dated April 20, 2001), which he distributed to Committee members. In 2001, the California legislature passed Senate Bill 680, a mandatory reporting law, and California's Office of Statewide Planning and Development (OSHPD) is now instituting a similar program, the Coronary Artery Bypass Graft (CABG) Mortality Reporting Program. Prior to SB680, participation in the program was voluntary. Dr. Shine noted that QI programs are unique to each state; however, there are lessons that can be shared.

The New York State Cardiac Advisory Committee has been in existence for more than 25 years and started as a CON committee. Dr. Shine was appointed Chair in 1994. An expert from outside the State of New York chairs the New York State Cardiac Advisory Committee, with another four to five members also from out of state. Utilizing expertise from outside minimizes internal conflicts of interest as new programs and policies are established. Out-of-state members are also helpful as site visitors.

According to Dr. Shine, a key element of success for the New York program was an alliance with Edward L. Hannan, Ph.D., Professor at the University at Albany who assisted with the statistical analysis and risk adjustment, forming the template for the reports. It is essential to perform risk adjustment for meaningful results. In New York, risk factors are applied to the performance of individual institutions and physicians. The risk factors are based on actual experience versus a theoretical construct, and vary from year to year. The approach used has been to collect data, especially on mortality, for all patients; identify risk factors each year; and then apply the risk factors to individual institutions and surgeons throughout the state. The database now contains a large amount of data (about 20,000 patients with CABG procedures and 40,000 with percutaneous transluminal coronary angioplasty procedures), which is regularly mined for research. Investigators have access to the data. Initially the information was intended to be confidential; however, following a *Newsday* Freedom of Information (FOI) lawsuit, the institutional information was made public, but not the individual data. Dr. Shine felt that institutional performance improved as a result of publication.

It has been found in New York's experience that there have been no changes in the way physicians refer or the way managed care organizations (MCOs) purchase services as a result of publication of information on hospitals. MCOs still purchased the cheapest care. Referrals out of state did not increase. However, there has been a significant change in the governance of the hospitals. One such result has been the reduction in the number of "low volume" surgeons operating. These "low volume" surgeons often had the highest mortality rates.

Regular audits of the data take place. Dr. Shine noted that some audits are conducted on a random basis; some are conducted when disagreements occur between the hospital and report data, or as flags are raised. Those cases require audit before publication of the data. Generally, when an outlier hospital (more than two standard deviations above the mean) occurs, it is a system-of-care issue (a problem in the institution, not a random variation).

Initially, the program in New York started with data reporting only on CABG; however, it has now been extended to coronary angioplasty, pediatric cardiac surgery, and valve surgery. New York is now exploring an evaluation of the outcomes of care for acute myocardial infarction. Currently, the NY State Advisory Committee is examining freestanding angioplasty (that is, hospitals performing angioplasty without cardiac surgery).

A third meeting of the Steering Committee was held on June 12, 2002. James L. Field, DBA, Director, Cardiovascular Roundtable, Advisory Board Company in Washington, D.C., briefed the Steering Committee on future trends in cardiovascular services. Dr. Field, also a member of the Steering Committee, said that the industry is in turmoil for a number of reasons:

- ***Drug-Eluting Stents***

  This new technology has the prospect of leading to an increasing transition of cardiology cases from the operating room (OR) to the cath lab, with less morbidity and time spent in the hospital. Restenosis now develops in about 20 – 30 percent of cases, requiring at least one or more additional interventions in one year. Drug-eluting stents have the potential to address the restenosis problem by giving off, or "eluting," drugs to the site of the blockage, aimed at preventing the restenosis from occurring and possibly eliminating the need for additional procedures at the blockage site. The cost of this new technology will be significantly more than the bare-metal stent. This added cost will take cath labs into the red on these cases. The low margins that currently exist in labs will dissipate and hurt hospitals. A trailing effect will result from the potential of drug-eluting stents to eliminate a significant number of cardiac cath lab procedures for in-stent restenosis. A major financial impact on the cardiac service line is expected if cardiac surgery volumes (coronary artery bypass grafts) also decrease 50 percent in the next five years as some expect.

- ***Primary Angioplasty in Hospitals without On-Site OHS***

  The ability of a hospital to perform primary angioplasty without open heart surgery (OHS) back-up is dependent on each state's regulations and varies by state. However, providers are increasingly demanding such capabilities due to the widely reported results of the C-PORT trial. For some states, there is no barrier to performing such procedures. Soon providers will also be requesting the ability to perform elective cases without surgical back-up, and movement toward performing elective cases will have a domino effect. Cath labs are becoming the emphasis rather than cardiac ORs. Hospitals with cath labs but no surgery may partner for back-up with a hospital that performs OHS.

- ***Volumes Overall***

With an aging population, the total number of cardiac procedures is increasing. The general sense is that there is a flat or declining curve for OHS volume, especially CABG, while interventions in the cath lab are increasing. This pattern of increase is expected to accelerate earlier and more dramatically with the introduction of drug-eluting stents.

- ***Pacing or Cardiac Resynchronization Therapy***

Pacing, or cardiac resynchronization therapy, is the latest technology in treating heart failure, and has been successful in trials so far. It may be appropriate for those 20-30 percent of CHF cases with conduction defects, and it may be combined with implantable cardioverter defibrillators (ICD), with the potential for many patients to receive it. Hospitals will probably lose money on each device they implant. Manufacturers have strategically priced the devices so that the hospitals will lose about $3,000 - $5,000 per procedure (the device costs about $16,000, and implanting it costs the hospital about $18,000 to $20,000, including the device, leads and care). This will come on the heels of the other financial impacts.

- ***Number of New OHS Programs***

Within the last year, the Advisory Board identified announcements or recent openings of 54 programs across the U.S. There are approximately 2 to 3 new OHS/Interventional programs opening or planning to open each week around the country. This rate of increase in programs is shocking with the impact of drug-eluting stents not being factored into the analysis of need. The new programs are driven by market competition rather than the need to serve a population that does not now have access to care and needs to travel miles and miles to receive it. This process is having an impact on administrators by siphoning off the business of existing programs and reducing volume expectations to around 200 cases per year (in the case of one program, 150 per year). Average program volumes are currently around 200 to 225 cases; if this continues to drop any further, volumes will drop below the quality threshold of 200. Weeding out low-volume programs is not likely to happen, raising both political and quality issues.

- ***Shortage of Cardiologists***

Two or three years ago, there was considered to be a general oversupply of cardiologists. However, today there is a shortage, especially in "outlying" areas. Access is better in wealthy suburbs. A successful program relies on the right number of cardiologists to refer patients into the program. A lack of cardiologists will impede the growth of a program.

A joint meeting of the Steering Committee and the Quality Measurement and Data Reporting Subcommittee is scheduled for October 2, 2002. At that meeting, William Nugent, M.D., Chief of the Cardiothoracic Surgery section at the Dartmouth-Hitchcock Medical Center

in Lebanon, New Hampshire, will discuss the Northern New England Cardiovascular Disease Study Group (NNECDSG). Dr. Nugent is a founding member of NNECDSG.

Figure 2

Advisory Committee on Outcome Assessment in Cardiovascular Care

Steering Committee

Chairman

James Scheuer, M.D.
Professor of Medicine and University Chairman Emeritus
Department of Medicine
Albert Einstein College of Medicine/Montefiore Medical Center
Bronx, New York

Membership

Robert R. Bass, M.D.
Executive Director
Maryland Institute for Emergency Medical Services Systems
Baltimore, Maryland

William A. Baumgartner, M.D.
Cardiac Surgeon
Vice Dean, Clinical Affairs and Cardiac Surgeon-in-Charge
The Johns Hopkins Hospital
Baltimore, Maryland

Georges C. Benjamin, M.D. (Ex-Officio)
Secretary
Department of Health and Mental Hygiene
Baltimore, Maryland

Luther T. Clark, M.D.
Chief of Cardiology
SUNY Health Sciences Center at Brooklyn
Brooklyn, New York

Donald H. Dembo, M.D.
President, MD Chapter of the American College of Cardiology
Johns Hopkins Cardiology at Timonium
Baltimore, Maryland

James L. Field, DBA
Executive Director, Cardiovascular Roundtable
Advisory Board Company
Washington, D.C.

Scott Friedman, M.D.
Cardiologist
Memorial Hospital of Easton
Easton, Maryland

Bartley Griffith, M.D.
Cardiac Surgeon
University of Maryland Hospital
Baltimore, Maryland

Jeffrey D. Jones, M.D.
Cardiologist
Washington County Hospital
Hagerstown, Maryland

Steve B. Lowenthal, M.D.
Chief Medical Officer
St. Agnes HealthCare
Baltimore, Maryland

Thom Mayer, M.D.
Chairman, Department of Emergency Medicine
Fairfax Hospital
Falls Church, Virginia

Mark Midei, MD.
Cardiologist
St. Joseph Medical Center
Towson, Maryland

Luis Mispireta, M.D.
Cardiac Surgeon
Chief, Division of Cardiac Surgery
Union Memorial Hospital
Baltimore, Maryland

Hilary T. O'Herlihy, M.D.
President, MedChi Board of Trustees
Glen Burnie, Maryland

Eugene R. Passamani, M.D.
Cardiologist
Vice President, Quality
Suburban Hospital
Bethesda, Maryland

Sidney C. Smith, Jr., M.D.
Director, Center for Cardiovascular Science and Medicine
University of North Carolina Health Care
Chapel Hill, North Carolina

David O. Williams, M.D.
Director, Cardiovascular Laboratory and Interventional Cardiology
Rhode Island Hospital
Providence, Rhode Island

Note: Vahe Kazandjian, Ph.D. served on the Steering Committee until June 2002.

Background

Maryland has long recognized the value of reliable health data and has a strong commitment to collecting and using data to support health policy development. Data are required to measure performance, understand underlying components of care that contribute to differences in outcomes, and develop strategies for on-going quality improvement. Strategies designed to improve the quality of cardiovascular services have been developed at the national, state, and regional levels over the past decade. Table A-1 (in the Appendix to the Interim Report) profiles the clinical areas studied, quality improvement elements, participation requirement, sponsorship and goals of existing quality improvement programs.

These existing programs focus primarily on quality improvement related to CABG surgery, interventional cardiology, and AMI. Initiatives designed to support quality improvement for CABG surgery have emphasized outcome measurement and reporting (e.g., in-hospital mortality). In some instances, these programs have focused on improving processes of care. AMI efforts have been geared toward improving processes by reducing the gap between clinical guidelines and actual practice. The programs profiled on Table A-1 include initiatives where participation is voluntary as well as programs where participation is mandatory. The sponsorship of these quality improvement programs ranges from government agencies to physician associations to businesses and, in a number of instances, consists of a partnership of the various stakeholders.

At the national level, the Society of Thoracic Surgeons (STS) has developed a database on CABG surgery. This voluntary national database, which contains over one million CABG cases, provides cardiac surgeons and hospitals with the ability to benchmark practice and outcomes. The Guidelines Applied in Practice (GAP) initiative of the American College of Cardiology in Southeastern Michigan is a quality improvement approach that seeks to incorporate national guidelines into care processes by creating tools and systems that reinforce the use of evidence-based therapies.[1] The National AMI Project, sponsored by the Centers for Medicare and Medicaid Services (CMS), focuses on strengthening appropriate care processes for patients hospitalized with AMI, including early administration of aspirin, early administration of beta-blocker, and smoking cessation counseling during hospitalization.

At the state level, New York began collecting data to analyze the quality of care provided to CABG patients in 1989.[2] As part of this effort, a Cardiac Advisory Committee, composed of surgeons, cardiologists, and researchers, was formed to advise the Department of Health on the quality and appropriateness of cardiac surgery in New York. Since 1990, the New York State

[1] Mehta, RH et al. Improving the Quality of Care for Acute Myocardial Infarction: The Guidelines Applied in Practice (GAP) Initiative. *Journal of the American Medical Association*. Vol. 287 No. 10, March 13, 2002, p. 1269-1276.

[2] Hannan, EL Kilburn, H. Racz, M. Shields, E. and Chassin, MR. Improving the Outcomes of Coronary Artery Bypass Surgery in New York State. *Journal of the American Medical Association*. March 9, 1994, Vol. 271, No. 10: 761-766.

Department of Health has annually released hospital-specific data on volumes and mortality rates to the public. In 1992, the publicly released information was expanded to include surgeon-specific risk-adjusted mortality rates. Beginning in 1996, reporting was expanded to include hospital and physician-specific data on percutaneous coronary interventions (angioplasty).[3] Similarly, the Pennsylvania Health Care Cost Containment Council initiated the release of public reports on CABG surgery beginning in 1992. These reports, like the reports from New York, contained information about risk-adjusted patient mortality for both hospitals and individual cardiac surgeons. The most recent report in this series also includes risk-adjusted mortality and length of stay data for enrollees in selected health plans.[4] More recently, the Pacific Business Group on Health and California Office of Statewide Health Planning and Development worked together to develop the California CABG Mortality Reporting Program.

Another approach to improving quality has been undertaken in the New England region. The Northern New England Cardiovascular Disease Study Group, a voluntary research consortium composed of physicians, researchers, and hospital administrators in Maine, New Hampshire, and Vermont, has developed a three-part collaborative approach to reducing CABG mortality that involves: feedback of outcome data, training in continuous quality improvement (CQI) techniques, and site visits to other medical centers. One assumption of this model is that the health care organizations and systems within which professionals practice can always improve and that one approach to foster this improvement is to establish a process for continuous monitoring and feedback.[5][6]

Purpose of the Subcommittee

The Subcommittee on Quality Measurement and Data Reporting is studying and making recommendations to the Steering Committee on issues related to the approach, structure, content, and funding of a Maryland cardiovascular quality improvement program and database. The subcommittee is reviewing a variety of approaches to improving the quality of cardiovascular services at national, state, and regional levels, and focusing on eight fundamental questions:

- What should be the scope of a cardiovascular quality improvement program and database in Maryland?
- On what elements of cardiovascular health care services should such a program focus – on their structure, their processes, or their outcomes?
- What data are required to measure current performance, and how should these data be risk-adjusted?
- What are the pros and cons of mandatory versus voluntary participation in a statewide quality improvement program of data collection and analysis?

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[3] New York State Department of Health, *Percutaneous Coronary Interventions (Angioplasty) in New York State: 1995-1997*, released July 2001, p. 3.
[4] Pennsylvania Health Care Cost Containment Council, *Pennylvania's Guide to CABG Surgery 1994-1995: Information About Hospitals, Cardiac Surgeons, and Health Plans.* May 1998.
[5] Donaldson, MS. Ed. *Measuring the Quality of Health Care*. National Roundtable on Health Care Quality. Institute of Medicine, January 1997.
[6] O'Connor, GT and Malenka, DJ, *The Northern New England Cardiovascular Disease Study Group: Recent Studies 2000-2001*.

- Who should sponsor the quality improvement data collection program: physicians and the facilities or systems with which they are affiliated, state government, or a partnership between the two?
- What are the pros and cons of the various methods and target audiences for reporting the data collected in such a statewide program? Should the data be collected and analyzed to educate physicians, or to educate consumers? In what format should the data and analysis be presented, and how should it be made public in accordance with federal and state laws?
- How should this effort be funded?
- By what process should the program's data elements and information reporting standards be updated and revised on a continuing basis?

Subcommittee Composition

The Quality Measurement and Data Reporting Subcommittee includes 17 members representing the disciplines of cardiac surgery, cardiology, outcomes research, biostatistics, clinical data management, and quality assurance. A list of subcommittee members is provided in Figure 3.

Brief Biography: Subcommittee Chairman

Luis Mispireta, M.D, chairs the Quality Measurement and Data Reporting Subcommittee. Since 1994, he has served as Chief of the Division of Cardiac Surgery at Union Memorial Hospital in Baltimore, Maryland. He also serves as Chairman of the Cardiovascular Performance Improvement Committee at Union Memorial Hospital and the Medical Director of Cardiac Services for the Western Maryland Health System in Cumberland, Maryland. Other current appointments include serving as Chairman of the Thoracic and Cardiovascular subsection of the District of Columbia Medical Society. Dr. Mispireta received his Doctor of Medicine degree from Cayetano Heredia University, Rimac in Lima, Peru. He served his internship and residency in general surgery at the Washington Hospital Center and fellowship in cardiothoracic surgery at George Washington University Hospital, Children's Hospital, and the Washington Hospital Center in Washington, D.C.

Accomplishments

The Quality Measurement and Data Reporting Subcommittee held its first meeting on June 6, 2002. At that meeting, members discussed the charge to the subcommittee from the Steering Committee and received resource materials providing overviews of several national and state quality improvement programs, including the STS Adult Cardiac Surgery national database, the Northern New England Cardiovascular Disease Study Group, and state-level outcomes measurement and reporting systems from New York and Pennsylvania. Following preliminary discussion, it was the consensus of the subcommittee to focus initial efforts on cardiac surgery and hospital-based interventional cardiology procedures.

At its second meeting on July 31st, the Quality Measurement and Data Reporting Subcommittee of the Advisory Committee on Outcome Assessment in Cardiovascular Care discussed a draft survey to collect information about Maryland hospital cardiac care data systems, and a draft outline of the subcommittee's report. Luis Mispireta, M.D., chairman of the subcommittee, reported on efforts to develop a consensus among the directors of the cardiac surgery programs in Maryland concerning the most effective and appropriate database for improving outcomes, and the best means of implementing statewide data collection and analysis. At its July 31st meeting, the Quality Measurement and Data Reporting Subcommittee approved the creation of a work group to examine further the data consortium model. The Cardiac Surgery Data Work Group met on September 19th to hear a presentation on issues regarding the confidentiality and public release and issuance of quality improvement data.

The subcommittee heard presentations on the National Cardiovascular Data Registry of the American College of Cardiology, and the National Adult Cardiac Surgery Data Base and Outcomes Program of the STS at its September 17, 2002 meeting. Dr. Eric Peterson of the Duke Research Institute, which manages data collection activities for the STS database, briefed the subcommittee on the design, organization, and management of the data elements collected in the National Adult Cardiac Surgery Data Base and Outcomes Program. He noted that several states are moving to mandate the participation in the STS survey by their cardiac surgery programs. According to Dr. Peterson, STS provides a distinct set of advantages. It is a well-established database, with well-known elements, and can provide significant experience as well as both national and regional benchmarks for comparisons. Its risk adjustment framework includes a range of variables that have proven useful as benchmarking measures. Its software is relatively simple, the institutions themselves can run it, and it provides a vocabulary and set of measures useful in discussions with patients. Dr. Ralph Brindis also briefed the subcommittee on the American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR) at the September 17, 2002 meeting. He reviewed the evolution of the ACC-NCDR and discussed how the performance and outcome measures collected offer valuable data for quality improvement and policy development.

Appendix A-3 includes summaries of the June 6th, July 31st, and September 17th meetings of the Quality Measurement and Data Reporting Subcommittee. A summary of the September 19, 2002 meeting of the Cardiac Surgery Data Work Group is also provided in Appendix A-3.

Figure 3

Advisory Committee on Outcome Assessment in Cardiovascular Care

Quality Measurement and Data Reporting Subcommittee

Chairman

Luis Mispireta, M.D.
Cardiac Surgeon
Chief, Division of Cardiac Surgery
Union Memorial Hospital
Baltimore, Maryland

Members

Diane Alejo
Data Center Management/Cardiac Surgery
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Vice Dean, Clinical Affairs and Cardiac Surgeon-in-Charge
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Susan L. Glover
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John New
Director, Quality Management
Maryland Institute for Emergency Medical Services Systems
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Karen Sweeney, RN, BSN
Manager, Clinical Data Systems
Sinai Hospital of Baltimore
Baltimore, Maryland

Douglas H. Wilson, Ph.D.
Director, Planning, Business Development
and Government Relations
Peninsula Regional Health System
Salisbury, Maryland

Daniel Woronow, M.D.
Cardiologist
Holy Cross Hospital
Silver Spring, Maryland

Interventional Cardiology Subcommittee

Background

Maryland hospitals performed almost 11,000 coronary angioplasty cases in 2001. The evolving use of coronary angioplasty in treating patients with coronary heart disease raises a number of important health policy issues. Among those issues is whether there is sufficient evidence to warrant changing current state health policy to permit hospitals with cardiac catheterization facilities to perform limited angioplasty procedures (i.e., primary angioplasty). With on-going technical improvements in coronary angioplasty procedures, it is also important to review policies governing the requirement for on-site cardiac surgical backup for elective angioplasty cases.

The *Maryland State Health Plan: Specialized Health Care Services-Cardiac Surgery and Therapeutic Catheterization Services* requires hospitals providing coronary angioplasty services to have on-site cardiac surgical backup. This policy reflects the advice of Maryland cardiologists and cardiac surgeons. The American College of Cardiology and the American Heart Association (ACC/AHA) national guidelines for the performance of angioplasty recommend that hospitals performing elective coronary angioplasty have cardiac surgery services available on-site.

The State Health Plan also includes procedures for exempting certain research projects from the policy requiring co-location of cardiac surgery and angioplasty services. Under these exemption procedures, the former Maryland Health Resources Planning Commission approved a request from Johns Hopkins University to permit selected Maryland hospitals participating in the Atlantic C-PORT clinical trial to perform primary angioplasty under the protocols of this research project. Hospitals participating in this clinical trial may perform primary angioplasty without the requirement for on-site cardiac surgical backup. This exemption was originally granted for two years from an effective date of January 15, 1996, and has been extended at the request of Johns Hopkins University since that time.

Between its initiation and December 1998, the C-PORT project enrolled more than 400 patients in a randomized clinical trial comparing primary angioplasty with medical therapy. At the time the C-PORT clinical trial was originally designed in 1996, there was limited experience in using the technique of coronary angioplasty to treat patients with acute myocardial infarction. Although there remain important questions on the role of primary angioplasty in treating acute myocardial infarction, this therapy has gained widespread acceptance among cardiologists as the preferred approach for treating acute ST-segment elevation myocardial infarction when it can be performed rapidly. More recently, the use of primary angioplasty in treating acute myocardial infarction has been further improved and reinforced by the addition of coronary stents and potent antiplatelet agents, the GpIIb/IIIa receptor antagonists. Given these developments, the C-PORT project stopped randomizing patients in August 1999. At present, the C-PORT project is a registry. The Maryland Health Care Commission acted in April 2002 to extend the exemption for the C-PORT project through July 2003. This extension will provide the opportunity for the Commission to consider the recommendations of the Advisory Committee on Outcome Assessment in Cardiovascular Care on whether and under what conditions primary angioplasty

should be permitted at hospitals without on-site cardiac surgery prior to updating the State Health Plan.

Purpose of the Subcommittee

The Subcommittee on Interventional Cardiology is conducting a detailed review of the results of the C-PORT project, the ACC/AHA guidelines, and other relevant research and developing recommendations to the Steering Committee on the types of hospitals that should perform primary angioplasty. In addition, the subcommittee is reviewing the policy of providing elective angioplasty services only in hospitals with on-site cardiac surgical services. Specifically, the subcommittee on Interventional Cardiology is studying and developing recommendations to the Steering Committee on the following issues:

- Should state health planning policy be modified to permit hospitals to perform primary angioplasty without the requirement for on-site cardiac surgery?
    - How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?
    - What institutional resources are required for a primary angioplasty program?
    - What are the program development requirements for a primary angioplasty program?
    - Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
    - What process and outcome measures should be used for on-going quality assessment?
    - Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?

- Should state health planning policy be modified to permit hospitals to perform elective angioplasty without the requirement for on-site cardiac surgery?
    - Is there evidence that current policy restricts availability of elective angioplasty services to Maryland patients?
    - How do outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery?
    - Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?
    - How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital?
    - What process and outcome measures should be used for on-going quality assessment?

- Is there a relationship between volume of elective angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
- Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?

Subcommittee Composition

Figure 4 provides a list of the Interventional Cardiology Subcommittee members. This subcommittee includes 26 members representing the disciplines of cardiology, cardiac surgery, planning, and emergency medical services.

Brief Biography: Subcommittee Chairman

The Subcommittee on Interventional Cardiology is chaired by David O. Williams, M.D. Dr. Williams is Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. He is a Professor of Medicine at the Brown University School of Medicine and a Member of the Cardiac Care Advisory Committee for the Rhode Island State Department of Health. Dr. Williams served on the American College of Cardiology/American Heart Association Committee to Revise the 1993 Guidelines for Percutaneous Transluminal Coronary Angioplasty. Other current appointments include the Executive and Steering Committees of the Registry for Percutaneous Transluminal Coronary Angioplasty and the Balloon Valvuloplasty Registry of the National Heart, Lung, and Blood Institute; Interventional Cardiology Test Committee of the American Board of Internal Medicine; and Chair of the Cardiac Catheterization Committee of the American College of Cardiology. Dr. Williams received his Doctor of Medicine degree from Hahnemann Medical College and served his internship and residency in internal medicine at Hahnemann Hospital in Philadelphia, Pennsylvania. He completed his fellowship in cardiology at the University of California School of Medicine in Davis, California.

Accomplishments

The Interventional Cardiology Subcommittee of the Advisory Committee on Outcome Assessment in Cardiovascular Care held its first meeting on September 4, 2002, at which the members discussed the charge, structure, and timetable of the subcommittee, and a proposed work plan and process. (A summary of the September 4th Subcommittee meeting is provided in Appendix A-3.) The subcommittee approved the preparation of a "state of the evidence" paper as part of its process of reviewing policies governing primary and elective angioplasty. This paper will document medical research to date on the questions posed in the charge to the subcommittee regarding both primary and elective angioplasty services. In addition, the subcommittee identified other types of data that will be required to complete its analysis, including information of the volume of AMI patients, data on travel times and distances between Maryland acute care hospitals, availability of interventional cardiologists and other required staff, and information on how other states are addressing health policy in this area.

The next meeting of the Interventional Cardiology Subcommittee is scheduled for October 16, 2002. At that meeting, the subcommittee will hear a presentation from Thomas Aversano, M.D. regarding the experience of hospitals participating in the C-PORT trial and registry.

Figure 4

Advisory Committee on Outcome Assessment in Cardiovascular Care

Interventional Cardiology Subcommittee

Chairman

David O. Williams, M.D.
Director, Cardiovascular Laboratory and
Interventional Cardiology
Rhode Island Hospital
Providence, Rhode Island

Members

Robert R. Bass, M.D.
Executive Director
Maryland Institute for Emergency
Medical Services Systems
Baltimore, Maryland

George Bittar, M.D.
Interventional Cardiologist
Union Memorial Hospital
Baltimore, Maryland

Sridhur Chatrathi, M.D.
Capital Cardiology
Lanham, Maryland

Charles Cummings, M.D.
Cardiologist
Mid-Atlantic Cardiovascular Associates
Westminster, Maryland

Michael Fiocco, M.D.
Cardiac Surgeon
Union Memorial Hospital
Baltimore, Maryland

Candice Fonke, RN
Director, Cardiology
Peninsula Regional Medical Center
Salisbury, Maryland

James L. Field, DBA
Executive Director, Cardiovascular Roundtable
Advisory Board Company
Washington, D.C.

Scott Friedman, M.D.
Cardiologist
Memorial Hospital of Easton
Easton, Maryland

Frank Gravino, M.D.
Cardiologist
Holy Cross Hospital
Silver Spring, Maryland

Bartley Griffith, M.D.
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Keith M. Lindgren, MD.
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Steve B. Lowenthal, M.D.
Executive Vice President/Chief Medical Officer
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Baltimore, Maryland

Mark Midei, MD.
Cardiologist
St. Josephs Medical Center
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Catherine L. Monge
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Hilary T. O'Herlihy, M.D.
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James K. Porterfield, M.D.
Division Head, Cardiology
GBMC HealthCare
Baltimore, Maryland

Figure 4 (Continued)

Advisory Committee on Outcome Assessment in Cardiovascular Care

Interventional Cardiology Subcommittee

Bernard Rubin, M.D.
Baltimore Heart
Randallstown, Maryland

Mitchell Schwartz, M.D.
Medical Director, Medicine Initiative
Anne Arundel Medical Center
Annapolis, Maryland

Dominic Seraphin
Vice President
Business Development
St. Joseph Medical Center
Towson, Maryland

Sidney C. Smith, Jr., M.D.
Director, Center for Cardiovascular Science & Medicine
Professor and Chief of Cardiology
University of North Carolina Health Care
Chapel Hill, North Carolina

Karen Stair
Director, Cardiovascular Services
Western Maryland Health System
Cumberland, Maryland

Long Term Issues Subcommittee

Background

One of the key issues in planning for the system of specialized cardiac care services is to assess the likely impact of trends that will shape the future health care environment. Those trends include the potential impact of advances in understanding how to prevent heart disease and how to prevent a heart attack as well as advances in the clinical management and treatment of clinical and sub-clinical heart disease.

Although many of the risk factors for coronary heart disease, including gender, age, and family history, cannot be altered, there is considerable evidence associating certain lifestyle factors with an increased risk of developing heart disease. Factors strongly implicated in heart disease by medical research include cigarette smoking, hypertension, diabetes, and hypercholesterolemia. Other risk factors include physical inactivity, diet, obesity, and alcohol dependence and abuse.[7] While a variety of factors have contributed to the declines experienced in heart disease mortality rates, the increased emphasis on and recognition of the importance of healthier lifestyles has clearly played an important role. Despite this encouraging trend, it is likely that heart disease will remain a leading cause of death and disability for the foreseeable future. Heart disease is one of the priorities listed in the state's Health Improvement Plan for 2010, a consensus document published by the Department of Health and Mental Hygiene. Those priorities are linked to the focus areas in the national Health People 2010 report.

Purpose of the Subcommittee

The Subcommittee on Long Term Issues will identify topics for additional study and develop proposals to further evaluate key policy issues. The feasibility of developing programs that address other issues in cardiovascular health and disease, including racial and ethnic disparities in cardiac services, primary and secondary prevention (including treatment of patients with diabetes and/or hypertension), risk factor detection and treatment, early identification and treatment of heart attacks, and treatment of patients after ischemic events is also being considered by the Subcommittee on Long Term Issues. Specifically, the subcommittee is considering the following issues:

- What progress has been made in Maryland toward year 2010 Healthy People objectives for heart disease deaths and risk factors?
- What steps can be taken to improve the management of care for congestive heart failure?
- What strategies should be developed to reduce racial and ethnic disparities in cardiac care services?

[7] U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, National Heart, Lung, and Blood Institute, *Report of the Task Force on Behavioral Research in Cardiovascular, Lung, and Blood Health and Disease*, February 1998, page 30.

- Should Maryland develop mechanisms to evaluate the adequacy of detection, prevention, and treatment of cardiovascular disease in the state? What elements should be addressed?
- What are the priorities for future research on the prevention and treatment of heart disease in Maryland? What grant funds are potentially available to support the research agenda? Who should lead efforts to obtain grant funds?

Subcommittee Composition

The 18-member Subcommittee on Long Term Issues includes members with expertise in cardiology, cardiac surgery, emergency medical services, public health, nursing, health education, and cardiac rehabilitation. A membership roster for the Subcommittee on Long Term Issues is provided in Figure 5.

Brief Biography: Subcommittee Chairman

Steering Committee member Eugene R. Passamani, M.D, chairs the Subcommittee on Long Term Issues. Dr. Passamani is currently Director for Cardiology and Medical Education at Suburban Hospital in Bethesda, Maryland. Effective January 2000, Dr. Passamani was elected to the Corporate Office of Vice President, Quality. Other current appointments include the Publications Committee, Task Force on Clinical Data Standards, and Database Research and Development Committee of the American College of Cardiology; President-Elect, Mid-Atlantic Affiliate, American Heart Association; and Member, Women's Health Initiative Working Group at the National Heart, Lung, and Blood Institute. Dr. Passamani is a graduate of the University of Michigan Medical School. He received postgraduate training in medicine as an intern at the Massachusetts General Hospital and completed his residency and cardiology fellowship at Washington University's Barnes Hospital in St. Louis, Missouri.

Accomplishments

The Long Term Issues Subcommittee held its initial meeting on June 5, 2002. At that meeting, the subcommittee discussed its charge, structure, and timetable. In addition, the subcommittee had background briefings on three major topics: the Healthy Maryland 2010 Project; the problem of heart failure in the United States; and a conceptual overview of a Prospective Heart Failure Patient Outcomes Clinical Trial study. First, Jeanette Jenkins, Director of the Office of Health Policy in the Community Health Administration of the Department of Health and Mental Hygiene briefed the subcommittee on the goals of the Healthy Maryland 2010 Project with respect to Cardiovascular Disease. While the previous goals of Healthy People projects had been to reduce or control health problems, under the 2010 project the primary goal is to eliminate health disparities and increase quality and years of healthy life. Healthy People 2010 is a comprehensive set of national health objectives for a ten-year period. These objectives are developed by a collaborative process and are designed to measure progress over time. According to Ms. Jenkins, there are 10 Leading Health Indicators (LHI) that reflect the major public health concerns in the United States. These indicators are: (1) physical activity, (2) overweight and obesity, (3) tobacco use, (4) substance abuse, (5) responsible sexual behavior, (6) mental health, (7) injury and violence, (8) environmental quality, (9) immunization, and (10)

access to health care. The second indicator, overweight and obesity, closely relates to the subject area of cardiovascular disease since overweight individuals are often affected with heart disease. Ms. Jenkins stated that the Healthy Maryland 2010 Project contains a Health Improvement Plan (HIP) that includes statewide modules as well as local modules.

Edward Kasper, M.D., Associate Professor of Medicine, Director, Cardiomyopathy and Heart Transplant Service, Johns Hopkins School of Medicine, presented a profile of the compelling problem of heart failure in the United States. In his subcommittee briefing, Dr. Kasper said that heart failure is a common pathway for other medical problems. Data show that 4.8 million people have heart failure in the United States. Of these diagnoses, 60 percent are due to coronary heart disease. Each year, between 400,000 and 700,000 new cases of heart failure are diagnosed. During the same period, 250,000 people die of heart failure. The number of heart transplants per year is approximately 4,000. Of those individuals hospitalized with heart failure, 80 percent are older than 65 years. As a result, more Medicare dollars are spent for heart failure than for any other diagnosis. In addition, $500 million is spent annually on drugs related to heart failure.

Dr. Kasper discussed a study that was conducted regarding 200 patients who were at high risk for hospital readmission for heart failure. The patients were randomized to multidisciplinary care or usual care for a six-month intervention at two clinical sites, Johns Hopkins Bayview Medical Center and Johns Hopkins Hospital. The results of the project showed there were 43 chronic heart failure (CHF) hospitalizations and 7 deaths in the intervention group. There were 59 CHF hospitalizations and 13 deaths in the usual care group. Both quality of life and quality of care improved with intervention. The cost was approximately the same in 1998 dollars. In concluding his presentation before the subcommittee, Dr. Kasper noted that heart failure is a disease of the elderly and is growing because the population is aging. Treatment for heart failure is also complex and at times difficult to administer.

A third background briefing at the June 5, 2002 Long Term Issues Subcommittee meeting was presented by Thomas Aversano, M.D., a cardiologist at the Johns Hopkins School of Medicine. Dr. Aversano presented information concerning his concept for a prospective, randomized comparison of usual care with multidisciplinary disease management for heart failure patients. He said that this Heart Failure Patient Outcomes Clinical Trial study could be very important in terms of understanding heart failure. According to Dr. Aversano, three areas should be considered when studying the care of heart failure patients: (1) assurance of quality, (2) access to care, and (3) containment of cost. In his view, there is now a poor track record concerning quality of care for heart failure patients. He suggested that the Commission could take several steps to promote better quality of care. These measures include: (1) supporting the concept of a patient outcomes trial relating to heart failure, (2) creating a necessary regulatory environment to allow studies to proceed, (3) becoming a "co-investigator," (4) assisting researchers in getting the attention of the Centers for Medicare and Medicaid Services (CMS), and (5) promoting the concept to the Maryland health care community. According to Dr. Aversano, there are several factors that help to make Maryland a good area to implement these measures. For instance, cooperative ties already exist through systems like the Cardiovascular Patient Outcomes Research Trial (C-PORT) project. Also, because Maryland is a small state geographically, it is easier to obtain assistance in gathering data. In addition to having two major

medical centers with clinical experts in the field of health failure, CMS, the agency responsible for administering Medicare, is located within the state.

The Long Term Issues Subcommittee held its second meeting on July 25, 2002. The subcommittee discussed recommendations regarding potential areas of focus for the subcommittee and a draft outline of the subcommittee's report. Focus areas recommended by subcommittee members for further discussion included: encouraging Maryland employers to cover the cost of health/fitness programs; development of a comprehensive approach to cardiovascular disease control to decrease the number of Marylanders who develop and progress to end-stage chronic heart disease; focusing on detection, control, and prevention of hypertension and obesity; education and research about the benefits of early defibrillation; educating physicians about the importance of using comparable generic drugs to contain health care costs; and aggressive primary and secondary strategies.

At their October 17th meeting, the Long Term Issues Subcommittee will have a briefing by Diane Bild, M.D., Medical Officer in the Division of Epidemiology and Clinical Applications at the National Heart, Lung, and Blood Institute. Dr. Bild will discuss the current state and future prospects for the detection of sub-clinical coronary artery disease. The subcommittee also plans to have a briefing on cardiovascular disease in underserved populations later this year.

Appendix A-3 includes summaries of the June 5th and July 25th meetings of the Long Term Issues Subcommittee.

Figure 5

Advisory Committee on Outcome Assessment in Cardiovascular Care

Long Term Issues Subcommittee

Chairman

Eugene R. Passamani, M.D.
Cardiologist
Suburban Hospital
Bethesda, Maryland

Members

Jerilyn Allen, Ph.D.
The Johns Hopkins University School of Nursing
Baltimore, Maryland

Jane R. Apson, M.S.P.H., Ph.D.
Director of Quality Information Systems
Worcester County Health Department
Snow Hill, Maryland

C. William Balke, M.D.
Chief, Division of Cardiology
University of Maryland Medical Center
Baltimore, Maryalnd

Irene Buadoo, M.D.
Director, Cancer and Tobacco Programs
Montgomery County Department of
Health and Human Services
Rockville, Maryland

Patricia Casals, R.N.
Clinical Nurse Manager, Interventional Cardiology
Peninsula Regional Medical Center
Salisbury, Maryland

Donald H. Dembo, M.D.
President, Maryland Chapter of the American
College of Cardiology
Johns Hopkins Cardiology at Timonium
Timonium, Maryland

Sheila Druck, R.N., BSN
Cardiovascular Fitness
St. Joseph Medical Center
Towson, Maryland

Stacey Fisher, M.D.
Medical Director, Women's Heart Program
Sinai Hospital of Baltimore
Baltimore, Maryland

Lynn Frank, F.A.C.H.E.
Chief of Public Health Services
Montgomery County Department of
Health and Human Services
Rockville, Maryland

Jeanette Jenkins
Director, Office of Health Policy
Department of Health and Mental Hygiene
Baltimore, Maryland

Aaron Kenigsberg, M.D.
Cardiologist
Holy Cross Hospital
Silver Spring, Maryland

Ruth Maiorana
Director, Health Education and Planning
Harford County Health Department
Bel Air, Maryland

George Moran, M.D.
Chief, Cardiology
Union Memorial Hospital
Baltimore, Maryland

Lisa Myers, R.N., M.S.
Director, Program Development
Maryland Institute for Emergency Medical Services
Systems
Baltimore, Maryland

Kenneth Rempher, RN
Advanced Practice Nurse
Sinai Hospital of Baltimore
Baltimore, Maryland

John M. Ryan, M.D.
Director, Office of Chronic Disease
Department of Health and Mental Hygiene
Baltimore, Maryland

Cheryl VanKuren
Program Manager, Cardiac Rehabilitation
Union Memorial Hospital
Baltimore, Maryland

Inter-Hospital Transport Subcommittee

Background

The ability to transfer patients from one hospital to another hospital is an important component of the system of care for treating cardiac patients. While many transports that occur between hospitals are for non-emergent reasons, in the area of cardiac care there are patients that require rapid transfer. Although the overall number of cardiac patients requiring rapid inter-hospital transport is comparatively small, some will potentially be eligible for primary angioplasty. For these patients, available data indicates that the effectiveness of the angioplasty intervention is directly related to the time between onset of the acute myocardial infarction and the initiation of the intervention. This factor, combined with the benefits of a system that promotes higher volume cardiac care programs, suggests that access to timely inter-hospital transport is of critical importance. With the growing acceptance and use of primary angioplasty to treat acute myocardial infarction, inter-hospital transport is an important component in planning an optimal system of cardiac care in Maryland.

Purpose of the Subcommittee

The Subcommittee on Inter-Hospital Transport is studying and developing recommendations to the Steering Committee on strategies for improving the transport of cardiac patients between hospitals. Specifically, the subcommittee is considering the following issues:

- Are there highly efficient systems in place in other states or countries that provide a model for Maryland? What are the components of the optimal inter-hospital transport system for cardiac patients? What specially trained staff is required to support the transport of emergency cardiac patients?
- How should an inter-hospital transport system be organized and funded?
- Should standard protocols be developed to guide the transport of emergency cardiac patients between hospitals? Who should develop them?
- What standard data elements should be collected on inter-hospital transports for cardiac patients to benchmark current system performance and establish improvement goals? Who should collect the data?
- Who should lead an effort to develop an improved statewide inter-hospital transport system?

Subcommittee Composition

The 17-member Subcommittee on Inter-Hospital Transport includes members with expertise in cardiology, cardiac surgery, emergency medical services, critical care nursing, and air and ground medical transport systems. In addition to representatives from major providers of cardiac services throughout Maryland, the subcommittee includes experts from the adjacent

jurisdictions of Washington, D.C. and Virginia. A list of Inter-Hospital Transport Subcommittee members is provided in Figure 6.

Brief Biography: Subcommittee Chairman

Steering Committee member Jeffrey D. Jones, M.D., chairs the Subcommittee on Inter-Hospital Transport. Since 1994, Dr. Jones has been a cardiologist on the staff of Washington County Hospital in Hagerstown, Maryland. He currently practices with Hagerstown Heart, P.A. Other current appointments include the Food and Drug Administration's Cardiovascular Devices Advisory Panel. Dr.Jones is a former member of the National Institutes of Health (NIH) Steering Committee for the Antiarrhythmic versus Implantable Defibrillator Study and the NIH National Heart Attack Alert Program Coordinating Committee. Dr. Jones received his Doctor of Medicine degree from the University of Maryland and served his internship and residency in internal medicine at Washington Hospital Center in Washington, D.C. He completed his fellowship in cardiology at the University of South Florida in Tampa, Florida and the Washington Hospital Center.

Accomplishments

The Inter-Hospital Transport Subcommittee of the Steering Committee held its first meeting on August 22nd. The subcommittee discussed its charge, structure, and timetable. Cheryl Y. Bowen, M.S., M.A., R.N., Director of Commercial Ambulance Licensing and Regulation for the Maryland Institute for Emergency Medical Services Systems, gave a presentation on the Maryland Neonatal Intensive Care Transport System. The subcommittee also heard information about the development of a private inter-hospital transport system by three hospitals in the Baltimore City/Baltimore County area that provides cardiac surgery and interventional cardiology services.

The second meeting of the Inter-Hospital Transport Subcommittee is scheduled for September 30, 2002. At the September 30th meeting, the subcommittee will have a series of briefings on ground and air inter-hospital transport systems currently in use in Maryland and adjacent states. Patricia Casals, R.N. will brief the subcommittee on the inter-hospital transport system developed by Peninsula Regional Medical Center. Edward Rupert, Director of Air and Ground Transport for the Washington Hospital Center, will review data on the helicopter transport service provided by MedStar Health. Todd Walker, President of the Mid-Atlantic Region for Rural Metro Corporation, will provide an overview of critical care transport data in Maryland as well as adjacent states. The subcommittee will also receive additional information about the development of an inter-hospital transport system by three Baltimore area hospitals at the September 30, 2002 meeting.

Appendix A-3 includes a summary of the August 22, 2002 meeting of the Inter-Hospital Transport Subcommittee.

Figure 6

Advisory Committee on Outcome Assessment in Cardiovascular Care

Inter-Hospital Transport Subcommittee

Chairman

Jeffrey D. Jones, M.D.
Cardiologist
Washington County Hospital
Hagerstown, Maryland

Members

Valerie Allen, R.N.
Director, Cardiac Patient Care Services
Sinai Hospital of Baltimore
Baltimore, Maryland

Andy Armetta
Director, Property and Fleet Management
LifeBridge Health
Baltimore, Maryland

Cheryl Y. Bowen, M.S., M.A., R.N.
Director, Commercial Ambulance Licensing and Regulation
Maryland Institute for Emergency Medical Services Systems
Baltimore, Maryland

James Brown, M.D.
Cardiac Surgeon
University of Maryland Medicine
Baltimore, Maryland

Patricia Casals, R.N.
Clinical Nurse Manager, Interventional Cardiology
Peninsula Regional Hospital
Salisbury, Maryland

Carol Curran, R.N., M.S.
Director, Nursing Critical Care and Heart Institute
St. Joseph Medical Center
Towson, Maryland

Lucy A. Ferko, R.N.
Administrative Director, Cardiac Services
St. Joseph Medical Center
Towson, Maryland

Michael Franklin
Vice President, Professional Services and Product Line Development
Shady Grove Adventist Hospital
Rockville, Maryland

Eric Lieberman, M.D.
Cardiologist
Associates in Cardiology, P.A.
Silver Spring, Maryland

Thom Mayer, M.D.
Chairman, Department of Emergency Medicine
Fairfax Hospital
Fall Church, Virginia

Henry Meilman, M.D.
Chief, Cardiac Catheterization Lab
Union Memorial Hospital
Baltimore, Maryland

Mark G. Nelson, M.D.
Chief of Cardiac Surgery
Sacred Heart Hospital
Cumberland, Maryland

Stephen Pollock, M.D.
Cardiologist
Mid-Atlantic Cardiovascular Associates
Towson, Maryland

Edward Rupert
Director, Air and Ground Transport
Washington Hospital Center
Washington, D.C.

Todd Walker
President, Mid-Atlantic Region
Rural Metro Corporation
South Euclid, Ohio

Carole Woehlke, R.N.
Director, Cardiac Catheterization Lab
Union Memorial Hospital
Baltimore, Maryland

Appendix A-1

Overview: National, Regional, and State Cardiovascular Quality Improvement Programs and their Attributes

Table A-1: Overview: National, Regional, and State Cardiovascular Quality Improvement Programs and their Attributes

Quality Improvement Program	Clinical Areas Studied	QI Elements (Structure, Process, Outcomes)	Participation Requirement (Mandatory or Voluntary)	Sponsorship	Goal
•NATIONAL PROGRAMS STS National Database	CABG, Other Cardiothoracic	Process Outcomes	Voluntary	The Society of Thoracic Surgeons	To establish the "gold standard" worldwide for process and outcomes analysis related to cardiothoracic surgery
Guidelines Applied in Practice (GAP)	AMI	Structure Process Outcomes	Voluntary	ACC, Peer Review Organization, provider network	To improve quality of cardiovascular care by reducing the gap between care recommended in guidelines and that delivered in practice
VA Continuous Improvement in Cardiac Surgery Program	CABG, valves and great vessel surgery	Process Outcomes	Mandatory	VA Administration – Federal Government	To risk-adjust outcomes in cardiac surgery as a preliminary screening tool for evaluating and improving quality of care
VA Quality Enhancement Research Initiative in Ischemic Heart Disease	IHD: AMI, UA, CABG, PCI and lipids	Structure Process	Mandatory	VA Administration – Federal Government	To address the gap between guidelines-recommended therapies and actual VA practice
Medicare Cardiovascular Cooperative Project	AMI	Process	Mandatory	CMS	To accelerate the decline in AMI mortality for Medicare patients
National AMI Project	AMI	Process	Mandatory	CMS	To lower the one-year mortality rate for Medicare beneficiaries following hospital admission for heart attack
Breakthrough Collaborative – 50 hospitals nationwide	CABG, Valve	Process Outcomes	Voluntary	Institute for Healthcare Improvement	To improve outcomes and reduce costs in adult cardiac surgery

Quality Improvement Program	Clinical Areas Studied	QI Elements (Structure, Process, Outcomes)	Participation Requirement (Mandatory or Voluntary)	Sponsorship	Goal
•**REGIONAL PROGRAMS** Northern New England Cardiovascular Disease Study Group	CABG, PCI, Unstable Angina	Process, Outcomes	Voluntary	Participating physicians, scientists and hospitals	To foster CQI in the care of patients with CV disease through the pooling of outcomes data and the study of process
•***STATE PROGRAMS*** New York	CABG, PCI	Outcomes	Mandatory	NYS Department of Health	To reduce operative mortality
Pennsylvania	CABG	Process Outcomes	Mandatory	PA Health Care Cost Containment Council – State Agency	To provide large purchasers and individual patients with information to be used in making health care decisions based on quality and value
New Jersey	CABG	Outcomes	Mandatory	NJ Department of Health	To reduce operative mortality
Minnesota	CABG	Process Outcomes	Voluntary	Minnesota Society of Thoracic Surgeons	To implement a CQI process to identify and improve variations in practice protocols and outcomes
Alabama	CABG	Process Outcome	Voluntary	Alabama PRO and CABG providers	To improve processes of care that affect outcomes
Connecticut	AMI	Process Outcome	Voluntary	State PRO, hospitals and physicians	To generate a database on AMI care for Medicare and non-Medicare patients that can be used to profile and improve care
Washington	CABG, PCI	Outcomes	Voluntary	Foundation for Health Care Quality (physician group)	To stimulate and inform internal quality improvement activities to improve health status outcomes
California	CABG	Outcome	Voluntary	Office of Statewide Health Planning and Development and the Pacific Business Group on Health	To provide comparative risk-adjusted mortality rates to hospitals, providers, purchases of care and patients and their families

Appendix A-2

Steering Committee Minutes

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

March 4, 2002
Medical School Teaching Facility
University of Maryland Medical School, 2nd Floor Atrium

Commissioners and Staff Present
James Scheuer, M.D., Chairman
William A. Baumgartner, M.D.
James L. Field, DBA
Scott Friedman, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Steve B. Lowenthal, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Eugene R. Passamani, M.D.
Sidney C. Smith, M.D. (by telephone)

Commissioners and Staff Present
Commission Chairman
Donald E. Wilson, M.D.

Commission Staff
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook

Consultant
Andrew G. Cohen

Committee Members Absent
Georges C. Benjamin, M.D. (Ex-Officio)

Members of the Public Present
Clarence Brewton, MedStar Health
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Wynee Hawk, Greater Baltimore Medical Center
Gary Jones, Shore Health System
Sandra Mann, Johns Hopkins Medicine
Martha Nathanson, LifeBridge Health
Jack Neil, Anne Arundel Medical Center
Vanessa Purnell, MedStar Health

1. Welcome, Opening Remarks, and Introductions

Donald E. Wilson, M.D., convened the meeting at 6.30 p.m. with a welcome to those present and introductions of James Scheuer, M.D., Chairman of the Advisory Committee; Barbara G. McLean, Executive Director of the Commission; and Pamela W. Barclay, the Commission's Deputy Director for Health Resources. Dr. Wilson briefly discussed the goals of the Commission in establishing the Committee. He noted that Dr. Georges C. Benjamin has been appointed as a member. Dr. Wilson announced that the Commission will appoint three additional members within the next few weeks. Committee members and Commission staff then introduced themselves.

2. Overview and Background

Ms. McLean provided a brief overview of the mission and vision of the Maryland Health Care Commission, referencing the *Report to the Governor: Fiscal Year 2001*. She also presented a brief description of the activities and programs of the Commission.

3. Review and Discussion of the Advisory Committee Charge, Structure, and Timetable

Advisory Committee Charge

Ms. Barclay briefly reviewed the charge of the Advisory Committee on Outcome Assessment in Cardiovascular Care, referencing material provided to the Advisory Committee. The Commission has requested that the Committee identify quality measures to assess outcome, study models available for improvement in cardiovascular care, review policies governing how cardiac services are organized, and identify strategies for developing inter-hospital transport for specialized cardiac care services.

Timetable

Ms. Barclay outlined the timetable for the Advisory Committee to submit an initial report to the Commission by July 1, 2002. The goal is to submit a final report to the Commission by January 1, 2003.

Dr. Sidney Smith asked about the likely starting times of the meetings, and whether the meetings are open to the public. Ms. Barclay said that the meetings are most likely to be in the evenings to fit everyone's schedules, but all members will be polled to find the most suitable times and dates. Ms. Barclay confirmed that the meetings of the Advisory Committee are open to the public.

Dr. Eugene Passamani asked whether the charge was limited to hospital-based services only. Ms. Barclay noted that a subcommittee will be established to study long-term issues, such as screening and prevention.

Dr. Passamani asked about the level of funds available to achieve the objectives set out, for example, the collection and analysis of data. Dr. Scheuer pointed out that the Committee would be short-lived; however, the continuing process will cost money. The committee will discuss and develop recommendations on how to fund an on-going quality improvement pocess.

Subcommittees

Subcommittees will be established to address the objectives of the Committee's charge. These will include Subcommittees on Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport. Ms. Barclay said that additional individuals will be invited to contribute to the subcommittees.

Dr. Scheuer invited the members of the Committee to recommend individuals who can make special contributions to the subcommittees. The recommendation should include supporting information.

Dr. William Baumgartner commented that some of the subcommittees would cover one or more issues raised by the Committee's charge.

Dr. Scheuer stated that the biggest impact relates to primary care and prevention and asked about recommendations on non-acute interventions. Dr. Smith expressed the view that the Committee should look at performance measures for non-acute cardiovascular care, adding that the criteria of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are moving in that direction. Dr. Luis Mispireta asked if the data reporting was to include all areas, angioplasty as well as surgery. Dr. Scheuer responded yes to Dr. Mispireta's question.

Mr. James Field commented that outcome data used by consumers is often different than that provided to clinicians. He further said one reporting method may not necessarily meet both needs. Dr. Scheuer responded that this is the type of issue that needs to be dealt with in the subcommittees and brought back to the Steering Committee. Dr. Scheuer added that some States have done both in regard to releasing outcome data to the public and clinicians, and that decisions need to be made considering the Freedom of Information Act.

4. Presentation: Overview of National, Regional, and State Quality Improvement Initiatives

Mr. Andrew Cohen presented a profile of national, regional and state quality improvement initiatives. He also explored a number of possible elements to be incorporated in a Maryland Cardiovascular QI Model. These included:

- Where Should CV QI be Focused? There is a continuum of care from prevention to medical treatment to procedures. Other states have focused on one or more areas, and Maryland needs to decide where it wants to focus.
- What Elements of QI? Different programs in other states include components ranging from structure to process to outcome.
  Dr. Baumgartner asked for clarification of the term "Round Robin" as a "process" element. Mr. Cohen explained that it is a method used by Northern New England to identify "best practices," where the group organized "round robin" site visits among the involved hospitals. Site visit teams from each hospital, consisting of cardiac surgeons, perfusionists, nurses, and administrators, reviewed how care was delivered at other centers.
- What Should be the Terms of Participation? Options available are voluntary or mandatory involvement; there are pros and cons for each.
- Who Should Sponsor? Options available include providers, partnerships and State, with potential combinations of the three options available.
- How Should QI Data be Reported? Maryland needs to decide whether to share outcome data with peers only or with the public as well. In States where mandatory reporting is required, data is shared with the public. Studies have found that the public has not necessarily changed the way they choose services based on the reporting of public data.

A sixth question was raised: Who will pay for it?

Dr. Mispireta suggested that the Committee does not need to think of this issue as a single unit. For example, data collection may be one cost, and data management may be another cost.

Dr. Passamani commented on the phrasing of "either/or" and suggested that a sequence of effort is required. He said that the aim is to help hospitals keep going in the right direction, and to nudge them away from making mistakes. The primary focus should be on the providers, as consumers may have difficulty interpreting the data.

Dr. Steve Lowenthal said that regardless of the intended target audience, the public would gain access to the information. He suggested the development of a system that will help practitioners, but inform the public. Dr. Scheuer confirmed this view by saying that New York originally intended its report only for providers, but a lawsuit resulted and the information became available to the public. Mr. Cohen described one state that established a private, not-for-profit organization to shelter or protect the data. Dr. Lowenthal said that the report should be open to the public, as ultimately the public will be concerned.

Mr. Field raised the issue of the burden and cost of data collection, and suggested the need to set firm objectives and reasons to collect. The current group has the benefit of other states' experiences and should draw on that.

Dr. Scheuer questioned how Maryland will know whether cardiovascular care has improved if the current quality of cardiovascular care in the state is not known.

Dr. Mispireta shared his experience of collecting data for 20 years, and said that once an institution has the infrastructure, data collection is easier to do. Dr. Mispireta added that most institutions already collect and use data internally. He said that all are concerned about physician profiles, but it is the way to improve the process. Dr. Passamani reiterated that the data must be collected carefully. Dr. Mispireta stated that this is an opportunity to collect unbiased data. Dr. Baumgartner felt that the process could be used as an academic exercise. Northern New England has done this extremely well; with two of the best medical schools in the country, Maryland could do likewise. Dr. Scheuer suggested a cost-benefit analysis could result from the process.

5. Future Meeting Schedule

Dr. Scheuer announced that the next meeting would be on Wednesday, April 17, 2002. Dr. Scheuer said that Kenneth I. Shine, M.D., has been invited to speak. Dr. Shine is President of the Institute of Medicine, National Academy of Sciences, and he chairs the New York State Cardiac Advisory Committee.

Dr. Scheuer discussed the necessity and process of the subcommittees and their charges. He asked each Committee member to serve on at least one subcommittee, and invited the members to nominate other appropriate candidates. Dr. Scheuer emphasized that it is hoped that by mid-June progress would have been made towards certain goals for the mid-year report.

Ms. Barclay asked the Committee members about the most efficient mechanism to communicate. The general consensus was by email. Another meeting will be planned for June after a poll is taken to identify a date and time.

Ms. McLean requested that the members provide the requested information within 2 weeks of the current meeting. Ms. Barclay said that the Commission wishes to involve as many people as possible in the subcommittee process and will also draw from a pool of persons who were interested in serving on the Steering Committee.

Dr. Scheuer asked if the Committee members would like to invite other speakers with experience in a particular subject matter. Dr. Bartley Griffith recommended Dr. Bill Nugent, Chief of Cardiothoracic Surgery at Dartmouth-Hitchcock Medical Center, who is an inspirational speaker and has experience in the process and the debate about voluntary versus mandatory reporting. Dr. Nugent works with the Northern New England Cardiovascular Disease Study Group, a regional collaborative model. Dr. Passamani seconded that recommendation. Dr. Baumgartner recommended Laurie Shroyer, Ph.D., who has worked within the federal Veterans Affairs (VA) system and is able to present statistical methods in a straightforward manner. Dr. Shroyer created the statistical modeling for risk adjustment with Karl Hammermeister, M.D. Dr. Scheuer reminded the group that the Committee members also have vast experiences, such as Dr. Smith, who could speak on the Guidelines for Percutaneous Transluminal Coronary Angioplasty.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7.40 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

April 17, 2002
Medical School Teaching Facility
University of Maryland Medical School, 2nd Floor Atrium

Committee Members Present
James Scheuer, M.D., Chairman
William A. Baumgartner, M.D.
Georges C. Benjamin, M.D. (Ex-Officio)
James L. Field, DBA
Scott Friedman, M.D.
Bartley Griffith, M.D.
Jeffrey D. Jones, M.D.
Vahe Kazandjian, Ph.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.
Mark Midei, M.D.
Luis Mispireta, M.D.
Hilary T. O'Herlihy, M.D.
Eugene R. Passamani, M.D.
Sidney C. Smith, M.D. (by telephone)

Commissioners and Staff Present
Commission Chairman
Donald E. Wilson, M.D.

Commission Staff
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Patricia Cameron
Susan Panek
Debbie Rajca
Colleen Lates

Members of the Public Present
Vanessa Aburn, Union Memorial Hospital
Angelyn B. Estwick, Master of Public Health Candidate, George Washington University
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Wynee Hawk, Greater Baltimore Medical Center
Gary Jones, Shore Health System
John J. Kennedy, M.D., Anne Arundel Medical Center
Sandra Mann, Johns Hopkins Medicine
Jack Neil, Anne Arundel Medical Center
James K. Porterfield, M.D., Greater Baltimore Medical Center

1. Call to Order and Introductions

Dr. Scheuer called the meeting to order at 6.30 p.m. Members of the Advisory Committee, the Chair of the Commission, and Commission staff introduced themselves. It was announced that three new members joined the Committee. Vahe Kazandjian, Ph.D. is the President of the Center for Performance Sciences, MHA: The Association of Maryland Hospitals and Health Systems; Thom A. Mayer, M.D. is the Chair, Department of Emergency Medicine,

Inova Fairfax Hospital; and Hilary T. O'Herlihy, M.D. is the President of the MedChi Board of Trustees.

2. Approval of the Minutes of the Previous Meeting (March 4, 2002)

On motion of Eugene R. Passamani, M.D., which was seconded by Scott Friedman, M.D., the minutes of March 4th were approved.

3. Presentation: Challenges in Developing a Maryland Cardiovascular QI Model

James Scheuer, M.D. introduced Kenneth I. Shine, M.D., President of the Institute of Medicine (IOM), National Academy of Sciences, and Professor of Medicine Emeritus at the University of California, Los Angeles (UCLA) School of Medicine, and Chairman of the New York State Cardiac Advisory Committee. Dr. Shine is UCLA School of Medicine's immediate past Dean and Provost for Medical Sciences. Currently, he is Clinical Professor of Medicine at the Georgetown University School of Medicine.

A distinguished cardiologist, Dr. Shine received his M.D. from Harvard Medical School and completed most of his advanced training at Massachusetts General Hospital (MGH), where he became Chief Resident in Medicine. Following his postgraduate training at MGH, he held an appointment as Assistant Professor of Medicine at Harvard Medical School. He moved in 1971 to the UCLA School of Medicine and became Director of the Coronary Care Unit, Chief of the Cardiology Division, and subsequently, Chair of the Department of Medicine. His many leadership roles have included President of the American Heart Association.

Dr. Shine prefaced his presentation on the experience in New York regarding the issues, pros and cons related to implementing a Cardiovascular QI Model by referring to a letter addressed by Dr. Shine to a California State Senator (dated April 20, 2001), which he distributed to Committee members. In 2001, the California legislature passed Senate Bill 680, a mandatory reporting law, and California's Office of Statewide Planning and Development (OSHPD) is now instituting a similar program, the Coronary Artery Bypass Graft Mortality Reporting Program. Prior to SB680, participation in the program was voluntary. Dr. Shine noted that QI programs are unique to each State; however, there are lessons that can be shared.

California collects data on pre-operative risk factors (e.g., ejection fraction, urgency of the procedure, age, and sex of the patient) and in-hospital surgical mortality associated with the CABG. As noted, hospitals are voluntarily providing the data for the program, at this time.

The New York State Cardiac Advisory Committee has a history of more than 25 years and started as a CON committee. Dr. Shine was appointed Chair in 1994. The New York Advisory Committee is traditionally chaired by someone from outside the State of New York, with another four to five members also from outside. Utilizing expertise from outside minimizes any internal conflicts of interest as new programs and policies are established. Out-of-state members are also helpful as site visitors.

In 1989, New York began to look at measuring outcomes. A key element of success was an alliance with Edward L. Hannan, PhD., Professor at the University at Albany who assisted with the statistical analysis and risk adjustment, forming the template for the reports. It is essential to perform risk adjustment for meaningful results. In New York, risk factors are applied to the performance of individual institutions and physicians. The risk factors are based on actual experience versus a theoretical construct, and vary from year to year.

The approach used since has been to collect data, especially on mortality, for all patients; identify risk factors each year and then apply them to individual institutions and surgeons throughout the state. The database now contains a large amount data (about 20,000 patients with coronary bypass procedures and 40,000 with PTCA procedures), which is regularly mined for research. Investigators have access to the data. Initially the information was intended to be confidential; however, following a Newsday Freedom of Information (FOI) lawsuit, the institutional information was made public, but not the individual data. Dr. Shine felt that institutional performance improved as a result of publication.

In 1989, the first year of reporting, the top tercile (one-third) of hospitals had a risk-adjusted mortality rate of 2.46% for CABG surgery, whereas the lowest tercile had a rate of 8.97%, a three-fold difference in outcome between the best performing and worst performing hospitals. By 1992, the quality gap had shrunk, with the highest tercile averaging a risk-adjusted mortality rate of 2.20%, while the lowest tercile had a risk-adjusted mortality rate of 2.8%. This trend continues with the State average at about 2.2%, the top tercile at 1.8%, and the lowest tercile at 2.7%.

It has been found in New York's experience that there have been no changes in the way physicians refer or the way managed care organizations (MCO) purchase services as a result of publication of information on hospitals. MCOs still purchased the cheapest care. Referrals out of state did not increase. However, there has been a significant change in the governance of the hospitals. One such result has been the reduction in the number of "low-volume" surgeons operating. These "low volume" surgeons often had the highest mortality rates.

Regular audits of the data take place. Some are conducted on a random basis; some are conducted when disagreements occur between the hospital and report data, or as flags are raised (for example, an increase in a diagnosis of ventricular aneurysms that may be evidence of "gaming"). Those cases require audit before publication of the data. Generally, when an outlier hospital (more than two standard deviations above the mean) occurs, it is a system-of-care issue (a problem in the institution, not a random variation). For example, one hospital with high risk-adjusted mortality rates was found to have good outcomes for elective patients, but poor outcomes for unstable patients admitted through the emergency room. An investigation found that the patients were not being stabilized before surgery, unlike elsewhere. Consequently, the system was changed so that unstable patients were stabilized in the emergency room prior to transfer to surgery. The outcomes improved dramatically. The surgeons were very capable technically in the operating room, but the process for getting the patients to the operating room was unsatisfactory.

Dr. Shine provided a number of other examples, demonstrating how quality data can be used to identify problem areas and improve outcomes. Citing a case in Rochester, he reiterated that the State must be alert to the issue of "gaming." He also noted the challenge of collecting 30-day mortality data.

Initially, the program in New York started with data reporting only on CABG; however, it has now been extended to coronary angioplasty, pediatric cardiac surgery, and valve surgery. New York is now exploring an evaluation of the outcomes of care for acute myocardial infarction. Thomas J. Ryan, M.D. is leading this effort. For myocardial infarction there are many more hospitals involved, with new issues to be covered. New York State provides software to the hospitals being evaluated so that they can perform their own analysis. The State encourages ongoing analysis; however, only about one-third do so. Most institutions wait to be notified with the data and then respond to the final assessment.

Results have shown that even at internationally renowned institutions, some individual surgeons have mortality rates three or four times higher than their colleagues. The New York Advisory Committee has no authority or responsibility beyond reporting the results to the institution when the institution itself, on the whole, is doing well. This lack of authority can be frustrating.

Currently, the NY State Advisory Committee is examining freestanding angioplasty (that is, hospitals performing angioplasty without cardiac surgery). The Committee looked first at the C-PORT protocols, which were found to be somewhat problematic during the trial; however, the registry is well set up. A task force has established protocols for such facilities under strict conditions, requiring quarterly reporting, including volumes and demographics.

The Committee derives its influence from being advisor to the State Department of Health. Although politics may enter into the outcome of a CON, the State has never approved a program that was medically unsafe.

As an example of how quality improvement may be addressed, Dr. Shine cited a recent focus on examining the equity of cardiac surgery for minorities in New York City. Currently, there are 14 programs offering catheterizations, and 10 performing cardiac surgery. It has been found that if catheterizations are performed at a full service hospital (that is, a hospital with cardiac surgery), minorities receive cardiac surgery at the same rate as the white population, if corrected for insurance coverage. However, if catheterizations are performed at a hospital without surgery, 82% (± 2%) of Whites receive surgery, high 60% for African-Americans, and 40% for Hispanics.

Dr. Shine described an experimental program involving Medicaid payment for procedures that meet the RAND criteria for necessity. Medicaid pays the hospitals well, but not the surgeons. The issue is whether the catheterization hospital or the surgery hospital will make the application to Medicaid.

Another example of how quality improvement may be addressed was cited. A hospital in Brooklyn currently has poor surgical outcomes, and it is evident that it has a low-volume

program and that the institution is not making a large investment in the program. Those who are aware of the program's predicament often opt out and go to another facility to receive care. In New York, strict criteria are in place when a new program is established. However, in order to improve quality, New York will issue a CON to another institution in this region, if it meets the criteria, despite the rules that prohibit a new program when an existing one is at low volume. The new program must meet strict guidelines for screening, evaluation, and other requirements for cardiac surgery. Clear objectives and goals for the program must be set out and followed. The CON is initially granted for five years only. It is hoped that introducing a new program will provide competition and an incentive to the poor performing hospital to improve.

Initially, many of the surgeons in New York were suspicious of the data reporting. It was argued that surgeons might not operate on the sickest patients for fear of increasing their mortality rates. It was also argued that more patients might be sent out of state for surgery if they were high risk. Analysis of the data contradicts both arguments.

Dr. Scheuer thanked Dr. Shine for his presentation and said some of the salient points to be learned were how data collection can be used for corrective action; how material can be used for research, and for new programs to address inequities in health care. Dr. Scheuer opened the floor for questions.

Luis Mispireta, M.D. asked for clarification of issues concerning the logistics of data collection and the definition of freestanding catheterization labs. Dr. Shine responded that freestanding catheterization labs referred to facilities performing primary angioplasty only, and not elective procedures; for example, the facilities involved in C-PORT were a source of data collection and analysis. In regard to data collection, Dr. Shine felt that a nurse coordinator was most frequently responsible for such duties. The Advisory Committee provides the software to assist in data collection and reporting; however, the institution was responsible for the actual collection and must bear the cost. Considering this, it is important to critically select data variables. For example, originally EKGs before and after were required. However, it was found to have no significant impact on outcome and was consequently removed to reduce unnecessary burden.

Dr. Mispireta thanked Dr. Shine for his comments, and also noted that cooperation is essential in such activities and that the data can be used as benchmarks with other states.

Dr. Shine responded that New York is trying to make the methodology as transparent as possible, and a sub-panel has been created to increase the exchange and identity of data. The Society of Thoracic Surgeons (STS) has done an outstanding job, but New York has the benefit of having data from all institutions. Dr. Shine has confidence in the majority of the data reported from the institutions. However, this highlights the importance of carefully selecting data variables. The pilot for Myocardial infarction (MI) which involves many more hospitals and possible risk factors, is being carried out initially with hospitals that are already involved with data collection, before expanding to rural hospitals, to streamline the process and to identify any potential problems.

Sidney C. Smith, M.D. commented that New York is a model program for exactly what the ACC/AHA committee aimed to do. He wanted to know how the State audits and adjudicates hospitals' results.

Dr. Shine informed those present that Dr. Smith has been a consultant for the New York Advisory Committee and New York has tried to use the ACC/AHA guidelines as much as possible. When data comes in from the hospitals, the Health Department staff reviews the data for completeness and flags any potential errors. If the results of the data are different between the hospital and health department, a meeting is organized to resolve the issues, and reasons are discussed for possible causes of increased or decreased mortality, or dramatic change in number of procedures. Following these meetings, there are rarely any difficulties in resolving data and interpretation issues. After an analysis and conclusion, the report is sent to individual hospitals to respond to results. After the initial release to the hospital, the hospital can challenge the analysis or conclusions. Nothing is released until the individual hospital has a chance to respond. Initially, this process was time-consuming; however, it is streamlined now.

Eugene R. Passamani, M.D. asked whether any false paths were taken (so that Maryland can avoid them); importance of the statistical center and how to set it up; and whether there are instances of special cause variation, where the cause of variation cannot be identified.

Dr. Shine responded that institutional reporting should not be secret. The Institute of Medicine has recommended that institutional reporting at the State level is valuable. Dr. Shine also said that asking for too much data should be avoided.

Dr. Shine reported that the data analysis is completed by an independent consultant outside of the health department. Neither the Department of Health nor the Committee can manipulate the independent statistician.

It is not always possible to identify reasons for variations. If there is a variation in one year only, there may be no real concern; however, when there is a variation sustained or outlier present over a number of years, there is more pressure to solve it. At this stage, site teams (typically consisting of cardiologist, surgeon and nurse) are sent to the institution, where it is often the nurse who will identify the problem. Unresolved variations will influence CON decisions, e.g., if a hospital requests an additional catheterization lab, the application will not be approved until the variation has been resolved. With this condition, variations are often more quickly resolved.

Hilary T. O'Herlihy, M.D. reported that as soon as the IOM report on racial and ethnic disparities in health care was released, MedChi, the Maryland State Medical Society, met with the Monumental City Medical Society, which represents African-American physicians. He said that disparity exists no matter the qualifications of the practitioner. Dr. O'Herlihy commented on the data reported by Dr. Shine regarding disparity in care for minorities, and questioned the provision for a CON in Brooklyn. It was clarified that Dr. O'Herlihy was referring to the recent IOM report, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care (March 20, 2002), whereas Dr. Shine was commenting on a New York City study. Dr. Shine also clarified that the 5-year trial period is for new programs only and is provided with specific

performance targets. The health department will not close the existing low quality institution, but it is hoped that with competition, there will be an incentive to improve performance.

Bartley Griffith, M.D. expressed concern about the confidence of risk adjustment, and shared his experience in Pennsylvania. Dr. Griffith said that patients may not always be appropriately risk-adjusted. He also said that single surgeon outliers are rare in today's world. Generally, government is not needed in such cases; the practice gets rid of them. Dr. Shine agreed that it is impossible to say that the data is perfect; however, he felt that the data is adequately risk adjusted. Dr. Shine added that data is a moving target, requiring modifications. Dr. Griffith expressed his concern that data made public to consumers may cause more harm than good. Dr. Shine commented that, overall, most institutions with risk adjustment have good outcomes. He reiterated that persistent outliers are not differences in risk adjustment, and that there is no evidence that physicians are avoiding difficult patients.

Dr. Griffith asked Dr. Shine to comment on the way the Northern New England Cardiovascular Disease Study Group handles data. Dr. Shine responded by saying that the New England program is very useful and has made a valuable contribution. It focuses on outcomes, identifying problems, and re-education and re-training issues. Dr. Shine said that the New England group handles its data differently. He stressed the need to look at and understand the system-of-care.

4. Update on Steering Committee and Subcommittee Membership

Pamela Barclay said that there had been an overwhelming response to membership on the subcommittees. The Commission contacted those who expressed an interest in the Steering Committee, as well as Steering Committee members. In the next couple of weeks, membership will be finalized, including Chairs for each subcommittee.

5. Review and Discussion of Subcommittee Charges and Work Plans

Dr. Scheuer referenced the charges and work plans, which were included in the meeting package. Dr. Scheuer requested any comments on each of the four charges.

Dr. Mispireta commented on the charge for the Subcommittee on Quality Measurement and Data Reporting, asking about the feasibility of data collection on prevention issues, especially in the hospital setting. He wondered whether it would be better addressed under Long Term Issues. Dr. Scheuer acknowledged Dr. Mispireta's concern and felt those issues should be discussed and resolved in the subcommittees.

William A. Baumgartner, M.D. asked for clarification of the data used in the Subcommittee on Inter-Hospital Transport. Ms. Barclay and Dr. Passamani clarified that the data is Baltimore data from 1999. Mark Midei, M.D. raised the issue about triage and EMS. He said that EMS data from the field influences this topic greatly; adoption of a trauma system model for cardiovascular care in the field is potentially volatile. It is, however, related. Dr. Scheuer felt that the issue could be blended with the issues of the Interventional Cardiology group.

Dr. Passamani commented on the Subcommittee on Long Term Issues, by saying that congestive heart failure, a serious and fairly common illness, should be mentioned more prominently.

There were no comments raised on the Subcommittee on Interventional Cardiology.

6. Future Meeting Schedule

Ms. Barclay announced that the next meeting will be on June 12, 2002 at 6.30 p.m. The location is to be determined. It is hoped that the subcommittees will meet once before the June 12 meeting. Ms. Barclay said that a couple of members have not indicated a preference for the subcommittee with which they wish to work.

Dr. Scheuer asked the members to let him or Ms. Barclay know whether they would like another speaker for the next meeting and whether they would like to recommend one. Commission staff will follow up regarding subcommittee preferences.

7. Other Business

There was no other business.

8. Adjournment

The meeting adjourned at 7.45 p.m.

Summary of the Meeting
of the
Advisory Committee on Outcome Assessment in Cardiovascular Care

June 12, 2002
Metro Executive Building
4201 Patterson Avenue, Conference Room 100
Baltimore, Maryland

Committee Members Present
James Scheuer, M.D., Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.
Luther Clark, M.D.
Donald Dembo, M.D.
James L. Field, DBA
Scott Friedman, M.D.
Jeffrey D. Jones, M.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

Members of the Public Present
Andy Cohen, Consultant
Lucy Ferko, St. Joseph Medical Center
Sean Flanagan, St. Joseph Medical Center
Gary Jones, Shore Health System
Cheryl Lunnen, Union Memorial
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

Dr. Scheuer called the meeting to order at 6:30 p.m. Members of the Advisory Committee and Commission staff introduced themselves.

2. Approval of the Minutes of the Previous Meeting (April 17, 2002)

On motion of Steve Lowenthal, M.D., which was seconded by Scott Friedman, M.D., the minutes of April 17th were approved.

3. Presentation: Future Trends in Cardiovascular Services

James Scheuer, M.D. introduced James L. Field, Director, Cardiovascular Roundtable, Advisory Board Company. The Advisory Board is a membership of 2,000 of the country's largest and most progressive health systems and medical centers. The Advisory Board is a

"think tank" in health care, publishing 50 major studies and more than 3,000 customized research briefs each year on progressive management and clinical practices in health care, including cardiovascular research. The Cardiovascular Roundtable, which tracks clinical and business trends and issues, focuses its research efforts on the economic and market developments in cardiovascular services. Hospitals comprise about 99 percent of the Board's business, and about 65 percent of the cardiac surgery and interventional cardiology centers in the United States are members of the Roundtable.

Dr. Field stated that it is not business as usual for Cardiovascular Programs. More events have coalesced to affect the programs. Technologies are coming and going. Cardiac services continue to grow, and are something all hospitals aspire to have. To date, cardiac surgery has been highly profitable. Profits from Medicare payments helped cardiac surgery programs generate a pool of money to cross-subsidize many other services in hospitals. After a period of being marginally profitable, catheterization laboratories have had higher profits, with stents, IIb/IIIa inhibitors, and Medicare coverage of stents. However, these margins are being offset by increasing technology costs.

Dr. Field said that the industry is in turmoil for a number of reasons:

1. Drug-eluting stents

This new technology has the prospect of leading to an increasing transition of cardiology cases from the operating room (OR) to the cath lab, with less morbidity and time spent in the hospital. Restenosis now develops in about 20 – 30 percent of cases, requiring at least one or more additional interventions in one year. Drug-eluting stents have the potential to address the restenosis problem by giving off, or "eluting," drugs to the site of the blockage, aimed at preventing the restenosis from occurring and possibly eliminating the need for additional procedures at the blockage site. There have been early spectacular results. In a USA trial (n= 1,100) revascularization was decreased with patient outcomes at 4 and 8 months showing only 4 percent with restenosis. These results are not as perfect as those of the European study, where none of 120 patients who were implanted with the drug-eluting stent experienced coronary restenosis in the six months following stent placement. At this stage, it cannot be determined if drug-eluting stents prevent or defer restenosis. Cordis, a division of Johnson & Johnson, is expected to introduce this technology in the first quarter of next year (2003). The best case scenario for approval is about six months; the worst case, still less than one year. The federal Food and Drug Administration (FDA) is expected to fast-track the review and approval of the application after a July submission of the trial results to FDA.

The cost of this new technology will be significantly more than the bare-metal stent. The current stent has a cost of $800 - $1,100, while the new drug-eluting stent is expected to cost $3,200 per stent. Cordis will initially have a monopoly on the product for some time to come, with no pricing competition. This added cost will take cath labs into the red on these cases. The low margins that currently exist in labs will dissipate and hurt hospitals. The conversion rate to use will be quick, causing a step function increase in cath lab costs.

A trailing effect will result from the potential of drug-eluting stents to eliminate a significant number of cardiac cath lab procedures for in-stent restenosis. A major financial

impact on the cardiac service line is expected if cardiac surgery volumes (coronary artery bypass grafts) also decrease 50% in the next five years as some expect.

Task groups have been set up to investigate the impact on cardiac surgery and hospital income. The current thought is to put on hold developing any extra capacity. Integrated systems in particular are not hiring cardiac surgeons or adding cardiac ORs. It is projected that a number of current CABG cases will instead go to the cath labs and interventional cardiologists will be able to treat them (e.g. patients with diabetes) more aggressively. This is a sobering development for cardiac surgery. It is expected that there will be a huge influx in cath lab cases and then the volumes will stabilize. It is thought that there will not be more single/double vessels or uncomplicated cases, but rather complicated cases, which are now treated in the OR. However, no one has examined in a disciplined fashion the type of disease that will be treated in the cath lab instead of the operating room; this issue requires closer examination.

2. Primary angioplasty – for hospitals with no OHS back-up

The ability of a hospital to perform primary angioplasty without open heart surgery (OHS) back-up is dependent on each State's regulations and varies by state. However, providers are increasingly demanding such capabilities, particularly due to the results and outcomes of the C-PORT trial. For some States, there is no barrier to performing such procedures. Soon providers will also be requesting the ability to perform elective cases without surgical back-up, and movement toward performing elective cases will have a domino effect. For example, TriStar Health System in Nashville has five or six hospitals doing primary angioplasty without on-site OHS. There is a low incidence of emergent surgery. The old rules about who should provide interventional cardiology are going by the wayside. Cath labs are becoming the emphasis rather than cardiac ORs. Hospitals with cath labs but no surgery may partner for back-up with a hospital that performs OHS.

3. Volumes overall

With an aging population, the total number of cardiac procedures is increasing. The general sense is that there is a flat or declining curve for OHS volume, especially CABG, while interventions in the cath lab are increasing. This pattern of increase is expected to accelerate earlier and more dramatically with the introduction of drug-eluting stents.

4. Pacing

Pacing or cardiac resynchronization therapy is the latest technology in treating heart failure, and has been successful in trials so far. It may be appropriate for those 20-30% of CHF cases with conduction defects, and it may be combined with implantable cardioverter defibrillators (ICD), with the potential for many patients to receive it. Hospitals will probably lose money on each device they implant. Manufacturers have strategically priced the devices so that the hospitals will lose about $3,000 - $5,000 per procedure (the device costs about $16,000, and implanting it costs the hospital about $18,000 to $20,000, including the device, leads and care). This will come on the heels of the other financial impacts.

5. Number of new OHS programs

Within the last year, announcements or recent openings of 54 programs were identified by the Advisory Board. This number is based on the number of programs identified, through

literature searches, business reviews and internet sources, to be in the final stages of planning, currently breaking ground or have been open for less than a year. There are approximately 2 to 3 new OHS/Interventional programs opening or planning to open each week around the country. This rate of increase in programs is shocking with the impact of drug-eluting stents not being factored into the analysis of need. The new programs are driven by market competition rather than the need to serve a population that does not now have access to care and needs to travel miles and miles to receive it. The established programs are under attack. Often the new programs are extensions of major centers, intended to refer ("feed") the more complex cases to the large tertiary centers. This process is having an impact on administrators by siphoning off the business of existing programs and reducing volume expectations to around 200 cases per year (in the case of one program, 150 per year). Average program volumes are currently around 200 to 225 cases; if this continues to drop any further, volumes will drop below the quality threshold of 200. Weeding out low-volume programs is not likely to happen, raising both political and quality issues.

6. Shortage of cardiologists

Two or 3 years ago, there was considered to be a general oversupply of cardiologists. However, today there is a shortage, especially in "outlying" areas. Access is better in wealthy suburbs. A successful program relies on the right number of cardiologists to refer patients into the program. A lack of cardiologists will impede the growth of a program.

When all of the above issues are considered, the outlook for cardiac programs is not as rosy as 2 to 3 years ago. From the patients' and cardiologists' points of view, better technology and skills of surgeons have increased quality and access. However, for hospital administrators, the financial impact could be severe.

Dr. Scheuer began the questions by asking Dr. Field to elaborate on ICD and changing indications. Dr. Field responded by saying that ICD is used in the prevention of sudden deaths. The new technology poses the question of implanting two devices or one super device. Manufacturers are pushing the high-end devices, with higher costs, and hospitals are not being paid adequately for such devices. The ability to pay for this technology is an issue for Medicare and private payers.

Ventricular assist devices and their technology do extend the survival of patients waiting for transplantation. They are considered meaningful; however, the current generation's problems include machine failure and sepsis. There is no money earmarked for the new generation of such technologies, which would generate billions of dollars of expenses. Medicare does not have the funds to pay for them.

Luther Clark, M.D. asked whether the devices were net losses for the hospitals. Dr. Field said that the losses flow through to other service lines, although no studies have been completed to demonstrate this. Hospitals are unable to recover direct costs of care and therefore there is a direct hit to the bottom line. In general, profitability is decreasing – reimbursements have gone down and costs have gone up. There is always a lag between new technology and Medicare reimbursements. For drug-eluting stents, the Medicare lag is expected to be approximately 2 years. Hospitals must cover the costs until then.

Donald Dembo, M.D. asked Dr. Field to comment on the primary and secondary prevention of heart disease and the long-term impact of the preservation of individuals with cardiovascular diseases. Dr. Field stated that he was not an expert in prevention. Referring to the March meeting of the American College of Cardiology, Dr. Dembo noted that the potential of statin drugs to reduce the incidence of cardiac events, an important consideration as the Medicare population grows. Dr. Scheuer stated that prevention is being addressed by the Long Term Issues Subcommittee, and that it is likely that primary and secondary prevention may have a more profound effect than some of these technologies on cardiovascular disease.

Dr. Scheuer thanked Dr. Field for his presentation, which he described as sobering and discouraging, but important.

4. Subcommittee Reports and Discussion

On behalf of the chairmen, Pamela Barclay presented the reports for Long Term Issues (Eugene Passamani, M.D.) and Quality Measurement and Data Reporting (Luis Mispireta, M.D.) subcommittees, both of which have met once. The Interventional Cardiology and Inter-Hospital Transport subcommittees have not met to date.

Each subcommittee has been set up so that there will be a liaison between the subcommittee and Steering Committee. The chairman of each of the subcommittees, who is a member of the Steering Committee, will bring back issues to the Committee and discuss recommendations.

Quality Measurement and Data Reporting

The subcommittee members discussed the charge that had been presented to them. There was a consensus that the starting point would be to survey existing OHS programs to see what data they were currently collecting (e.g., data submitted to the national Society of Thoracic Surgeons (STS) database) and how it was being used. Staff is drafting a survey, which will be reviewed by the subcommittee before being sent to the applicable hospitals.

Long Term Issues

The subcommittee received three background presentations as an introduction to the issues.

- Healthy People 2010 Project - Jeanette Jenkins, Director, Office of Health Policy, Community Health Administration, DHMH
- Congestive Heart Failure - Edward Kasper, M.D., Associate Professor of Medicine and Director of the Cardiomyopathy and Heart Transplant Service, Johns Hopkins School of Medicine
- Congestive Heart Failure: Patient Outcomes Clinical Trials - Thomas Aversano, M.D., Cardiologist, Johns Hopkins School of Medicine

Members were polled on other areas they would find beneficial to focus on.

The subcommittees also identified potential speakers, including William C. Nugent, M.D., of the Northern New England Cardiovascular Disease Study Group. It is hoped that he

will be available to present to the Steering Committee and the Quality Measurement and Data Reporting Subcommittee members. William A. Baumgartner, M.D. offered to assist by following up an email message to Dr. Nugent.

It was suggested that subcommittee updates should be added to the agenda for the subcommittees so that all subcommittees are aware of each other's activities, as there will be an overlap in some issues. Dr. Scheuer further suggested that the minutes of the meetings should be shared. Ms. Barclay agreed.

Dr. Scheuer suggested that the Quality Measurement and Data Reporting Subcommittee should look at the background information on all of the systems used across the country, including looking at the results and not just the mechanisms. Discussions are also needed on the effect of the programs on hospitals and doctors.

Dr. Scheuer suggested that the Get With the Guidelines (GWTG) project of the American Heart Association and Guidelines Applied in Practice (GAP) of the American College of Cardiology be reviewed and looked at in terms of how they can be used (i.e., whether the project should be recommended for use by all Maryland programs). Andy Cohen noted that discussion by the Long Term Issues Subcommittee is expanding beyond acute myocardial infarction (AMI) to congestive heart failure (CHF).

5. Future Meeting Schedule

Ms. Barclay stated that she would get the meetings of the Committee on the calendar for summer and fall.

Dr. Scheuer said that an interim report is due on July 1st and expressed some concern that the process has not moved as quickly as he had expected, especially in regard to the subcommittees, although he does appreciate the difficulty with time commitments. He asked the members for suggestions.

Dr. Clark suggested that meetings could be organized as teleconferences with some people meeting in person. Dr. Baumgartner suggested that planning several meetings in advance, rather than one at a time, might be beneficial. It is important to get the meetings on people's schedules. Dr. Scheuer suggested scheduling two subcommittees in an afternoon for about 2 hours, each with a good agenda, followed by two the following morning, and a Steering Committee soon after. Ms. Barclay said that the meeting of the Long Term Issues Subcommittee lasted two hours, with the meeting of the Quality Measures and Data Reporting Subcommittee being shorter. She has found that the evenings have generally been a better time to meet for the people involved. Dr. Scheuer felt that members could invest 2-3 hours one afternoon (e.g., 2:00-5:00 p.m., or 3:00-6:00 p.m.), and then revert to evenings. Dr. Baumgartner felt that most people are willing to put the time in, but such meetings would need to be planned ahead.

Robert Bass, M.D. suggested polling people and developing a regular pattern for the meetings (e.g., first Monday of the month). Dr. Baumgartner felt that teleconferences could be productive, if people come prepared and have done the appropriate reading of materials supplied.

Thom A. Mayer, M.D. also suggested supplementing meetings with emails to keep members up-to-date. Dr. Mayer added that conference calls work well especially after a face-to-face initial meeting.

Dr. Field inquired what the end-results of the subcommittees were, and suggested that there needs to be a strong sense of what needs to be done and to keep the work focused. Dr. Scheuer wondered whether forming an executive subcommittee would be valuable to work with the Chairmen and assist in the focus and progress. Ms. Barclay felt that the subcommittees have a sense of their purpose and all have been provided with the charges. She offered to review and refine the charges as needed. Barbara McLean stated that the two subcommittees that have met have made progress.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7:40 p.m.

Advisory Committee on Outcome Assessment in Cardiovascular Care

Summary of the
Joint Meeting of the Steering Committee and
Quality Measurement and Data Reporting Subcommittee

Wednesday, October 2, 2002
BWI Airport Marriott Hotel
1743 West Nursery Road
Baltimore, Maryland 21240

Steering Committee Members Present
James Scheuer, M.D., Chairman
Luis Mispireta, M.D.*†, Subcommittee Chairman
Robert Bass, M.D.
William A. Baumgartner, M.D.*†
Luther Clark, M.D.
Donald Dembo, M.D.
Scott Friedman, M.D.
Steve B. Lowenthal, M.D.
Thom A. Mayer, M.D.
Hilary T. O'Herlihy, M.D.
Eugene Passamani, M.D.

Subcommittee Members Present
Diane Alejo
James Brown, M.D.†
Mercedes Dullum, M.D.†
Susan Glover
Peter Horneffer, M.D.†
Teresa Kessell, RN
Sanjiv Lakhanpal, M.D.†
John New
Karen Sweeney, RN
Douglas Wilson, Ph.D.
Daniel Woronow, M.D. †

Cardiac Surgery Data Work Group Members Present
John Laschinger, M.D.
Anjum Qazi, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Patricia Cameron
Bridget Glazebrook
Colleen Lates
Susan Panek
Dolores Sands

Guest Speaker
William C. Nugent, M.D., Chief, Cardiothoracic Surgery at Dartmouth-Hitchcock Medical Center

Members of the Public Present
Sean Flanagan, St. Joseph Medical Center
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

James Scheuer, M.D. called the meeting to order at 5:30 p.m. Members of the Advisory Committee and the Quality Measurement and Data Reporting Subcommittee introduced themselves.

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*Member of the Quality Measurement and Data Reporting Subcommittee
†Member of the Cardiac Surgery Data Work Group

2. Approval of the Minutes of the Previous Steering Committee Meeting (June 12, 2002)

On the motion of William Baumgartner, M.D., which was seconded by Robert Bass, M.D., the minutes of the June 12th Steering Committee meeting were approved.

3. Review of Draft Interim Report to the Maryland Health Care Commission

Pamela Barclay presented the draft Interim Report of the Advisory Committee, and welcomed any comments or suggestions. The draft document will be submitted to the Commission at its October meeting.

Luther Clark, M.D. asked if the Interim Report included the formation of the subcommittees and the charges put to them. Ms. Barclay explained that the Interim Report is a progress report of the achievements to date of the Steering Committee and its subcommittees. The copy of the draft report provided to the committee members did not have the minutes attached, but the final version will include the minutes. Some of the subcommittees are still in the early development stage. The Advisory Committee on Outcome Assessment in Cardiovascular Care will submit a second report, which will be its final report and contain its recommendations to the Commission.

Dr. Scheuer asked the members to submit their comments on the draft document to Ms. Barclay by October 4th.

4. Presentation: Northern New England Cardiovascular Disease Study Group: William C. Nugent, M.D., Dartmouth-Hitchcock Medical Center

The purpose of the special, joint meeting was to hear a presentation by William C. Nugent, M.D., of the Dartmouth-Hitchcock Medical Center in Lebanon, New Hampshire. Dr. Scheuer introduced Dr. Nugent, who is a founding member of the Northern New England Cardiovascular Disease Study Group (NNECDSG) and is still active in the NNECDSG. The NNECDSG is a voluntary consortium of medical centers in Maine, New Hampshire, Vermont, and Massachusetts, and maintains a prospective registry of all patients receiving cardiac surgery in the northern New England region.

Dr. Nugent began his presentation on Outcomes Monitoring and Process Analysis for Regional Improvements by briefly discussing some new developments of the NNECDSG. At a recent meeting in Burlington, Vermont, discussions were held about reporting back to institutions their level of appropriateness (that is, doing appropriate operations based on national guidelines). A focus of the meeting was the analysis of stroke after coronary artery bypass graft (CABG) surgery, looking at ACC/AHA Guidelines for CABG Surgery and the data from a new perspective. The group is now looking at patient characteristics across databases (Society of Thoracic Surgeons (STS); New York State; Northern New England).

The NNECDSG did not start out with the aim of outcomes monitoring and process analysis. The group was initially created, in 1987, in response to a letter from the federal Health Care Financing Administration (HCFA, now known as the Centers for Medicare and Medicaid Services, or CMS) regarding the mortality rates of the hospitals. The group started as a defense against what it saw as an incursion on privacy by outside parties. The group exists to develop and exchange information concerning the treatment of cardiovascular disease. It is a regional, voluntary, multidisciplinary group of clinicians, hospital administrators, and health care research personnel – all of whom seek to improve continuously the quality, safety, effectiveness, and cost of medical interventions in cardiovascular disease. The group banded together to use its data to improve the outcomes of its patients and study those outcomes as it did so.

After collecting data for 2 ½ years, the group reported in 1991 that there was a significant variation in mortality rates between institutions in northern New England. This information came on the heels of a paper by John Wennberg, M.D. that looked at the variation in utilization of transurethal resection of the prostate for benign prostate hyperplasia. The feeling was that if there was variation in use of a procedure, there was likely to be variation in the outcome of the procedure. So the group studied CABG. The group found variation ranging from 3 percent to 6 percent or 2 percent to 5.7 percent, depending on whether the mortality data was adjusted or crude. (JAMA 1991; 266:803-809) Initially, there was concern about releasing the data to the public, especially in regard to reporters demanding to know which hospitals had the higher mortality rates. At that time, Dartmouth was the "high-mortality" institution. The reporters, however, allowed the institutions time to start working with the information and early initiatives to improve the mortality rates.

The NNECDSG set up a system for data feedback, providing reports on a regional, medical center and surgeon level. They invested in significant quality improvement training, turning to Donald Berwick, M.D. for guidance and training that included meeting skills and statistical analysis. The focus became to fix the process and to avoid laying blame, and to measure and use the data.

The region had to decide how to improve the processes. The group decided to invest in a very important initiative, a site visitation strategy. The options were to go outside or stay within the region. The decision was made to stay within the region. The group set up benchmarking visitation schedules and put multidisciplinary teams together at every institution to visit every other institution. The two to four hours spent traveling to other institutions provided a rare opportunity to get to know other members of a team. The teams discovered that all facilities were dealing with similar problems.

The data feedback reports placed the observed and expected rates along a time continuum. After two years, a change was seen with mortality rates improving; they dropped 24 percent as the group finished this first period. Every institution improved, the best as well as the worst in the region. (JAMA 1996; 275:841-846) Ghali suggested that the reduction seen in both northern New England and New York State would have happened regardless of quality improvement (QI) efforts, as similar improvement was found in Massachusetts, where there was neither a statewide, organized improvement effort nor dissemination of mortality data. (JAMA 1997; 277:379-382)

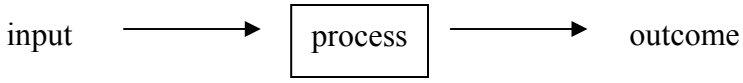
Peterson challenged the conclusion and examined Medicare data on both the total amount of improvement and the ultimate risk-adjusted mortality rate. He found that New York State and northern New England showed both the lowest overall mortality rates as well as the greatest improvements of any other state or region in the country. Peterson concluded that reporting of outcomes, whether voluntary and anonymous (northern New England) or mandatory and public (New York State), coupled with initiatives in quality improvement, is indeed effective in improving mortality rates after CABG. (JACC 1998; 32:993-999)

By 1995, the group had begun to answer the question about how many people were dying following CABG. The group felt that there were two more important questions that it needed to know more about: 1. Who dies following CABG? 2. How do they die following CABG? The group examined the risk of in-hospital death associated with emergency coronary bypass surgery and poor ventricular function. After looking at 31,549 consecutive patients who had surgery between 1992 and 2000, elective cases were found to have a low mortality rate (1-3%), based on their ejection fraction (EF), with the mortality rate of urgent cases increasing proportionately (2-5%), followed by emergency cases with the highest mortality rate (6-12%). The urgent population was defined as patients unable to be discharged from the hospital, but still able to be scheduled for surgery.

Raw numbers showed that most patients were in the elective and urgent category. The actual number of patients dying is greatest in the urgent cases. The highest percentage of all deaths fell in the urgent normal EF category (14.3%), although this is a low risk group. Based on their acuity in terms of preoperative EF, the urgent and elective patients make up about 75% of all deaths. Therefore, the greatest opportunity to have a real impact on quality improvement is for cases with normal EF who require urgent or elective care.

The NNECDSG led a regional retrospective review of CABG deaths in an effort to identify "mode of death." Mode of death is defined as the event that started the chain of events ultimately leading to the death of the patient. It is not the cause of death. The group looked at 4,000 consecutive deaths in the region. The most common mode of death (about 47% of patients) was found to be low cardiac output failure. Other modes of death included neurological, respiratory, dysrhythmia, and hemorrhage. The group further looked at how the surgeon may impact on mode of death. Based on adjusted mortality rates, surgeons in the region were profiled into terciles of risk (high, medium, and low). The study found that the incidence of low cardiac output explains the majority of difference in mortality rate between high risk and low risk surgeons. (Ann Thor Surg 1998; 66:1323-1328.) Fatal heart failure accounted for 80% of the difference in aggregate mortality rates, ranging from 1.9% in lowest surgeon mortality tercile to 4.0% in the highest tercile. Rates of other causes did not differ significantly across surgeon mortality terciles. Differences in rates of fatal heart failure could not be explained by differences in preoperative left ventricular dysfunction or other patient characteristics. That is, most of the difference in observed mortality rates across surgeons is attributable to differences in rates of heart failure.

Dr. Nugent described the diagram below as the take-home message of his talk. The NNECDSG focuses much of its work on looking at the process of care.



First order analysis involves looking at the outcome only, which relies on the input and process. Focusing on the process is considered second order analysis. Being profiled based on outcome alone tells nothing about how to change processes. The NNECDSG began to find process variables within its data set that clinicians could actually have control over and that would lead to a statistically higher likelihood of survival in its patient population.

By analyzing the regional database, four processes were identified that improved the outcomes of patients who had undergone CABG:

1. Aspirin pre CABG
2. IMA utilization
3. Adequacy of beta-blockers
4. Avoidance of anemia on bypass.

Aspirin (Ann Thor Surg 2000; 70: 1986-1990.)

A univariate analysis showed a 27% protective influence of just being on aspirin before surgery. The protective effect increased to 45% using multivariate analysis and correcting for such factors as body surface area and comorbidities. CABG patients using preoperative aspirin were less likely to experience in-hospital mortality. Aspirin use varied across the five centers in 1999-2000, from a low of 54.8 percent to 97.1 percent.

IMA and CABG (Circulation 2001; 103:507-512)

There is evidence that patients having coronary artery bypass graft surgeries with an internal mammary artery (IMA) have better long-term survival. In addition, it was found that IMA grafting has a strong protective effect on perioperative mortality. Adjusted data show that in-hospital mortality decreased from 4.9 percent to 2.2 percent. IMA use across five centers show a small range of 89.3 percent to 96.9 percent, compared to the national average of about 73 percent.

Pre-induction Heart Rate (Fillinger MP et al. accepted for publication in Anesth Analg, 2002)

This process variable came out of the anesthesia subcommittee. In-hospital mortality rate appears to be dependent on heart rate when the patient is rolled into the OR. If the patient's heart rate is allowed to go over 80 beats per minute (bpm), there is a significant increase in mortality (from 1.7 percent to 3.1 or 4.0 percent), even with adjusting for risk factors. The NNECDSG recently began a study to determine whether intervention at the time of surgery with a short-acting beta-blocker has an impact. Currently, three centers are tracking the number of patients found to be tachycardic who are being intervened upon at the time of surgery. Results show a range of 21.8 percent to 45.2 percent usage of beta-blockers.

Lowest Hematocrit on Cardiopulmonary Bypass (CPB) (Ann Thor Surg 2001; 71:769-776)

This process variable came out of the perfusion subcommittee. The NNECDSG wanted to find out what the impact of transfusion rates was on mortality rates in patients having CABG. Looking at elective patients, the likelihood of getting transfused ranged from 23 percent to 78 percent, depending on the institution. This wide variation suggested that the decision to perform a transfusion was based on the provider, not on the patient. It was found, after adjustment for preoperative differences in patient and disease characteristics, that the lowest hematocrit measured during CPB was significantly associated with increased risk of in-hospital mortality. In-house mortality ranged from 3.9 percent for patients with a lowest hematocrit of less than 19, to 1.6 percent for hematocrit levels above 25.

In response to those findings, there was a change in transfusion practices. In 1997, 26.5 percent of cases had a hematocrit less than 20, compared to only 9.2 percent regionally in the year 2000.

The NNECDSG publishes its findings and proselytizes at its meetings, but has no mandate on how centers should react to the findings. It is up to each to decide whether to change practices in light of new data. It is up to the individual cardiac surgeon to decide IMA use, the anesthesiologist to decide treatment of tachycardia in the operating room, the team to decide prospective or later transfusion, and the team or individual cardiologist to decide whether to keep the patient on aspirin.

Overall, there has been a decline in the regional mortality rate of the original five members of the consortium, from approximately 4.5 percent in 1987 to under 2 percent in 2000. This was achieved by conducting data feedback, QI training, and site visits, investigating mode of death, followed by process mapping and identifying process variables. The group has a grant from the American Heart Association (AHA) to specifically look at ways to deal with recognizing, diagnosing and treating low cardiac output syndrome.

Dr. Nugent concluded that understanding processes that determine outcome is critical for improvement, and that outcome reporting can be an effective improvement tool when coupled with process analysis. Large numbers of patients are needed to determine the fine changes when outcomes are already good. That mandates some level of collaboration, cooperation, and trust.

Dr. Nugent rhetorically asked why New York State and STS have not done the same level of process analysis. He reported that there are some unique qualities of the NNECDSG. There is no ambiguity in the purpose of the group – it is to improve outcomes, not to promote one institution over another, or to use that data either for or against an institution. There is no question about ownership and control of the data. The NNECDSG has established a safe place to work and provided a forum for discussion. The NNECDSG typically meets three times a year, usually a Friday afternoon followed by a Saturday morning. The members rotate meetings and travel expenses are funded out-of-pocket.

The NNECDSG focuses on three areas: clinical, administrative and academic. The clinical work currently involves data validation. The group validated for the third time its latest 30,000 patients, with a 99.7 percent validation. Mortality is based on in-hospital mortality, rather than 30-day mortality, because it is easier to validate. The group is now reconciling

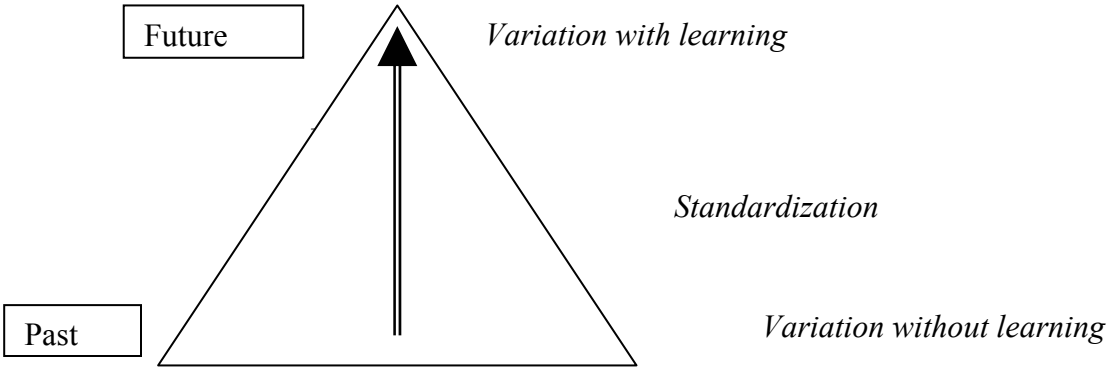
discrepant charts. The group currently has an AHA grant to work on the low output study. There is also a stroke initiative currently in progress. The group has completed a look at the timing of CABG and acute myocardial infarction (AMI) patients, reviewed its balloon utilization collaboration with two centers in Canada, and established a patient safety committee.

On the administrative side, there are three new members and now nine hospitals involved in the regional collaborative, with no political agenda. There is an agreed-upon format for sharing outcome data with third-party payers and other interested parties. This collaboration was between the executive committee of the NNECDSG and member hospitals' administrators. The outcome data cannot be used to promote one hospital as better than another, if there is no significant difference. All data are HIPAA compliant. Every hospital has informed consent and has gone through an institutional review board (IRB) procedure.

Academically, the NNECDSG has over 150,000 consecutive cases (including PCIs) and is observing the 11th anniversary of its first publication. There have been over 80 publications in various journals, including JAMA and JACC.

The NNECDSG represents a regional clinical collaboration. Dr. Nugent covered some points on how to start such a group. It is important to recognize that this is <u>not</u> recreational data collection, and that a little good data is better than a lot of bad data (i.e., high quality, low quantity). The key to maintaining a data collection group is to build credibility and trust. One way to achieve this is through publishing work in journals. The NNECDSG does not publish a paper unless there is at least one author from each organization in the consortium. Academics need to take a leading role in this. Finally, it is important to ensure that the process is working. Methods to know if it is working include: clinical use of data precludes "gaming" strategies, measurable practice changes occur based on data collected, and the group becomes equally concerned about outcomes for all hospitals. The nine hospitals currently have a regional CABG mortality rate of 1.7 percent; the difference is insignificant across all hospitals.

Dr. Nugent stated that a Rockwellian view of medicine is required, where the institutions need to work together as a team. It is a complex environment, working with a multidisciplinary group. He believes that the future will move to variation with learning.



Dr. Scheuer opened the floor for questions. Luis Mispireta, M.D. commenced the questions by confirming that the data presented was only for CABG. Dr. Nugent replied that the

data in his presentation was for CABG only, but data is also available for valve and PCI procedures.

Dr. Mispireta further asked about the difference between NNECDSG and STS. Dr. Nugent responded by saying that one major difference was regional versus national. There are also some small differences between the variables collected. Robert H. Jones looked at the variables of the two data collection groups, and found that the key variables that really determine 90 percent of the difference are the same. Dr. Nugent stressed that the difference is how the tool is used, rather than the tool (database) itself. The STS is focused nationally, while Dr. Nugent believes that you need to look regionally to make a difference.

Dr. Scheuer asked how the group assures uniformity and accuracy in the completion of the data set, and who pays for the data set. Dr. Nugent noted that the NNECDSG chose to use in-hospital mortality as an end point, rather than 30-day mortality as used by STS, because in-hospital mortality is easier to validate using administrative databases. However, administrative databases are difficult to risk stratify. Dr. Scheuer inquired about how ejection fraction and hematocrit are collected. Dr. Nugent informed the group that they are collected prospectively. Data is collected in medical records. Although every institution handles data collection differently, it is possible to have uniform reporting. Dr. Nugent added that the subjective interpretation is the place where the data tends to be the softest.

Dr. Nugent went on to say that it costs $400,000 to operate the consortium each year. Fifty percent of this is supported through grants, while the remaining 50 percent comes from dues. Institutions often include the dues in the budget for quality assurance because reports can go directly to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The consortium is a non-profit group, employing 2.5 analysts and 0.5 of an epidemiologist.

Donald Dembo, M.D. acknowledged the difficulty in validating mortality at 30 days, and asked about using quality of life markers for morbidity. Dr. Nugent reported that the SF 36 has been used in several situations, but is difficult to operationalize. Other functional health tools have been considered.

Dr. Clark asked how the NNECDSG built in the National Guidelines (ACC/AHA Guidelines for CABG Surgery) in order to determine appropriateness. Dr. Nugent reported that the Classes I, II, and III were used, as well as emergency versus non-urgent procedures, EF, and number of diseased vessels. Sometimes it was necessary to look at surrogates to determine the appropriateness of the treatment. Dr. Nugent said that he would like to see the multiple data sets consider changing the definitions of variables to match the guidelines.

Dr. Clark asked if the administration has the same “warmth” about the regional approach as the physicians. Dr. Nugent replied by recounting a situation he recently experienced. He was speaking to a CEO, whose hospital was recently listed as number seven in mortality rates. The CEO asked Dr. Nugent how he could get his hospital to be number one. In fact, the first hospital listed was ranked highest among the hospitals, then the next hospitals listed from two to seven were all statistically the same, i.e., significantly not different. The discussion indicated that

CEOs cannot talk to other CEOs about this issue, however, physicians can talk to other physicians about how to better their practices and be number one.

William Baumgartner, M.D. started by congratulating Dr. Nugent on the great work done by the NNECDSG. He asked whether it was difficult to reproduce the process of the group, and how the risk algorithm is accomplished. Dr. Nugent replied by saying that the data is risk stratified, using logistical regressions to determine variables and then appropriate weight. The main variables concentrated on to date have been in-hospital mortality and risk by EF and risk of low cardiac output. The NNECDSG created a Pocket Card Chart to assist in identifying risk, where physicians can circle appropriate risks, add up the weights and enter a value in the medical charts. This risk profile is part of the preoperative workup for all patients.

Dr. Mispireta commented on the tremendous infrastructure that must be required to set up such a service, and wondered if the NNECDSG has considered providing a service for other entities. Dr. Nugent said that the group has been approached before, but the infrastructure cannot support much more than the group at this time. Becoming a national warehouse would change the focus of the group. Dr. Nugent went on to say that the group has begun to move away from being a discussion group with presentations, to being more of an academic society with less productivity.

Steve Lowenthal, M.D. applauded the efforts of the NNECDSG, and wondered how it would work if hospitals were all located within 20 miles. Dr. Nugent was not sure if it would work as well, and thought it would be essential to be explicit about how the data would be used and to build credibility. The NNECDSG has a great research director, Gerry O'Connor, who does great statistical modeling and has managed to collect complete sequential regional data.

Eugene Passamani, M.D. noted that the group has been formed for over 10 years now, and wondered whether the group would do anything different if it were starting today. Dr. Nugent said the only thing the group may do differently is to have an electronic interface; it would not change anything in the format of the organization. However, Dr. Nugent feels that the group may need to start changing certain aspects as the focus on CABG becomes outdated. New areas of focus include PCI variables, such as groin hematoma, where the focus is not on mortality as an outcome.

Dr. Passamani also inquired about the center that recorded a low preoperative aspirin use (54%). Dr. Nugent replied that the data are descriptive, not prescriptive.

Dr. Clark inquired about the implications of the Freedom of Information Act on the data. Dr. Nugent said that the data is the group's data and is protected under peer review provisions. No one has challenged that. Dr. Nugent stressed the importance of publishing the data.

John Laschinger, M.D. asked how the database is compiled. Dr. Nugent said that the perfusionist fills out most of the data using a check-off list.

James Brown, M.D. asked Dr. Nugent for additional information about Gerry O'Connor, and what Dr. Nugent would do if NNECDSG were transplanted to Baltimore, with hospitals collecting STS data.

Dr. Nugent answered by stating that Gerry O'Connor is an epidemiologist who has remarkable consensus-building skills, statistical credibility, and considerable knowledge. The NNECDSG pays for and owns its data. Other hospitals are also collecting the same information in parallel. Dr. Nugent noted that the New York State system is set up so that its data is public, which can result in delays in data reports, when the hospitals could be acting to fix problems quicker. Finally, STS data is a good tool. Re-invent the tool only when necessary. Dr. Nugent reiterated that what is important is how the organization uses the tool, not the tool it uses.

Dr. Scheuer thanked Dr. Nugent for his very helpful presentation and for sharing his experience of working with the NNECDSG.

5. Subcommittee Reports and Discussion

Dr. Scheuer asked the chairman of each subcommittee to report on its group.

Quality Measurement and Data Reporting

Dr. Mispireta reported that he has had several telephone conferences regarding cardiac surgery quality and data issues. He hopes that the final concepts for the surgical side of the subcommittee's charge will be recommended at the next meeting of the Steering Committee. After finalization of the surgical data collection, the directors of the cardiac catheterization laboratories are expected to discuss their data collection. Dr. Mispireta noted that there are nine surgical centers, and a larger number of cath labs.

Long Term Issues

Dr. Passamani reported on the progress of the Long Term Issues Subcommittee. At the first meeting, Jeanette Jenkins presented background material on the Healthy People 2010 project. Edward Kasper, M.D. presented information on congestive heart failure (CHF). Tom Aversano, M.D. presented information on patient outcomes clinical trials related to CHF. Dr. Passamani said that CHF will have a growing importance in hospital treatment, and might be an area to focus on for process improvement. Drs. Kasper and Aversano each presented approaches on a regional level.

Dr. Scheuer asked if there had been any discussion of use of the various guidelines in the process. Dr. Passamani said that the subcommittee had not focused on the guidelines as such in its discussions of a cardiovascular disease model.

Diane Bild, M.D., M.P.H., of the National Heart, Lung, and Blood Institute (NHLBI), will be discussing the detection of sub-clinical coronary artery disease at the next meeting. Her presentation will include current methods and future prospects for detecting heart disease early, before it produces symptoms.

At the meetings, there has been some disagreement on the most cost-effective focus: primary or secondary prevention. However, some felt that it is hard to persuade well people to change and adopt healthier lifestyles. Dr. Passamani said that with a focus on CHF, it will be possible to identify subclinical disease, and target unserved populations, for example, minorities and those with low socioeconomic status (SES).

Dr. Passamani anticipates that the subcommittee will require a few more meetings before being able to put forward a recommendation to the Steering Committee.

Inter-Hospital Transport

Ms. Barclay reported on behalf of Jeffrey Jones, M.D., the Chairman of the Inter-Hospital Transport Subcommittee. The subcommittee held its first meeting on August 22nd. The subcommittee discussed its charge, structure, and timetable. Cheryl Y. Bowen, M.S., M.A., R.N., Director of Commercial Ambulance Licensing and Regulation for the Maryland Institute for Emergency Medical Services Systems, gave a presentation on the Maryland Neonatal Intensive Care Transport System. The subcommittee also heard information about the development of a private inter-hospital transport system by three hospitals in the Baltimore City/Baltimore County area that provide cardiac surgery and interventional cardiology services. At the second meeting, members looked at different transport systems in place across the state and region, and discussed the type of data needed to establish reasonable goals on how quickly people are transported.

Dr. Scheuer commented on the transport trial for emergency PCI, which had to be stopped because outcome was so significantly in favor of emergency PCI versus thrombolytics. Robert Bass, M.D. noted that transport by ambulance to an interventional center could work like that of the trauma system. There is potential to have information available to make decisions.

Interventional Cardiology

Ms. Barclay reported on behalf of the chairman, David O. Williams, M.D., Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital in Providence, Rhode Island. The Interventional Cardiology Subcommittee held its first meeting on September 4th, at which the members discussed the charge, structure, and timetable of the subcommittee, and a proposed work plan and process. The subcommittee approved the preparation of a "state of the evidence" paper as part of its process. Dr. Aversano, Director of the Atlantic C-PORT, is scheduled to discuss the results of the randomized trial comparing primary angioplasty with thrombolytic therapy at hospitals without on-site cardiac surgery, and the ongoing primary angioplasty registry established after the trial closed, at the next meeting on October 16th.

Dr. Dembo spoke about the impact of transport and the process of mechanical intervention versus thrombolytics. It appears obvious that the State should be triaging to centers that are capable of PCI, in a similar fashion to trauma centers. Trauma centers financially lose money; however, this is not the case for cardiac care. Dr. Bass reported that the trauma system in Maryland has been in operation for over 30 years, with other states having a system for not as long. Hospitals are concerned about losing cases and money.

Dr. Scheuer asked about the development of local PCI (i.e., PCI with no surgical back-up) and transport to centers, and how these can be integrated. He said that the two processes do not have to be adversarial. Dr. Misperita stated that diagnosis is the key indicator for where patients go. Dr. Passamani commented that stroke has the same issues; in the long run, the State wants patients to show up where the best care can be provided. This can be achieved by using a systematic response. Dr. Passamani stated that these services might be more expensive for some hospitals to take on.

Dr. Bass said that MIEMSS is looking at the triage of cardiac patients. Hospitals will need to make a commitment to see a patient in a stated timeframe. He noted, however, that the data on stroke is softer than that on cardiac. A systematic approach may be a way off for stroke. In response to a question concerning the issues faced by trauma centers around the country, Dr. Bass said that in Maryland some hospital administrators think that trauma centers are advantageous to their hospital, although they do bring in nonpaying patients.

6. Other Business

There was no other business.

7. Adjournment

The meeting adjourned at 7:20 p.m.

Appendix A-3

Subcommittee Minutes

Summary of the Meeting
of the
Quality Measurement and Data Reporting Subcommittee,
Advisory Committee on Outcome Assessment in Cardiovascular Care

June 6, 2002
Conference Rooms 108-109, Metro Executive Building
4201 Patterson Avenue, Baltimore, Maryland 21215

Subcommittee Members Present
Luis Mispireta, M.D., Chairman
Diane Alejo
James Brown, M.D.
Barbara Epke
Susan L. Glover
Peter Horneffer, M.D.
Teresa Kessell, RN
David Lowry
Cheryl Lunnen
John New
Karen Sweeney, RN, BSN
Douglas H. Wilson, Ph.D.
Daniel Woronow, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Dolores Sands
Debbie Rajca

Subcommittee Members Absent
William A. Baumgardner, M.D.
Mercedes K.C. Dullum, M.D.
Vahe Kazandjian, Ph.D.
Sanjiv Lakhanpal, M.D.

Guests Present
Andrew Cohen, Consultant

1. Welcome, Opening Remarks, and Introductions

Luis Mispireta, M.D., Chairman of the Quality Measurement and Data Reporting Subcommittee, called the meeting to order at 6:05 p.m., and welcomed the members of the Subcommittee to its first meeting. He asked subcommittee members and Commission staff to introduce themselves.

2. Overview and Background

Dr. Mispireta introduced Commission Executive Director Barbara G. McLean, for an overview of the Maryland Health Care Commission, and its role as convener of all of the interested parties in issues related to improving outcomes in cardiovascular services.
Ms. McLean expressed the Commission's gratitude for the time and expertise that Subcommittee members were giving to this initiative. She oriented the Subcommittee members to the

Commission and its goals, emphasizing its various efforts aimed at making marketplaces better, whether through a more rational, access-focused allocation of scarce health care resources through the State Health Plan and Certificate of Need, or by improving performance through data reporting. Ms. McLean also briefly explained the structure of the Advisory Committee, and its function as a steering committee, to guide the work of its four subcommittees, to receive and consider their plans and recommendations, and to forward recommendations for future activities and actions to the Commission. The present schedule for the work of the combined bodies is to have the subcommittees' work completed by next January.

3. Review and Discussion of the Subcommittee Charge, Structure, and Timetable

Dr. Mispireta introduced this discussion by noting that medicine takes a different perspective on making its discoveries and innovations known: unlike many disciplines, and because of its mission to heal and improve health, its impetus is to share its advances, by creating "best practices" models of care. This Subcommittee's role in the work and ultimate goals of the Advisory Committee is to find the best means of establishing a "best practice" model for cardiovascular services in Maryland, through the reporting and measurement of quality and outcomes of those services.

Pamela W. Barclay, Deputy Director of the Commission's Health Resources Division, reviewed the specific charge of the Quality Measurement and Data Reporting Subcommittee, in the context of the Advisory Committee's work. The Subcommittee will review a variety of approaches to improving the quality of cardiovascular services at national, state, and regional levels, and develop recommendations to the Advisory Committee on eight fundamental questions:

- What should be the scope of a cardiovascular quality improvement program and database in Maryland?
- On what elements of cardiovascular health care services should such a program focus – on their structure, their processes, or their outcomes?
- What data are required to measure current performance, and how should these data be risk-adjusted?
- What are the pros and cons of mandatory versus voluntary participation in a statewide quality improvement program of data collection and analysis?
- Who should sponsor the quality improvement data collection program: physicians and the facilities or systems with which they are affiliated, State government, or a partnership between the two?
- What are the pros and cons of the various methods and target audiences for reporting the data collected in such a statewide program? Should the data be collected and analyzed to educate physicians, or to educate consumers? In what format should the data and analysis be presented, and how should it be made public?
- How should this effort be funded?
- By what process should the program's data elements and information reporting standards be updated and revised on a continuing basis?

Subcommittee members have received resource materials including overviews of several national and state quality improvement programs, including the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery national database, the Northern New England Cardiovascular Disease Study Group, and state-level outcomes measurement and reporting systems from New York and Pennsylvania. For each program, staff has provided a table summarizing its focus, data elements, data collection and management processes, reporting mechanisms, provider access to data, required resources, magnitude in numbers of cases, and components Maryland might adopt. Examples of data collection instruments, including an updated STS form provided by Subcommittee member Diane Alejo, and examples of reports based on data collected and analyzed by the various programs were also provided with these summaries.

Dr. Mispireta began the discussion of these questions, noting that the Subcommittee needs to proceed as quickly as possible to the substance of the questions posed by its charge from the Advisory Committee, and to determine what elements and approaches of the existing quality and outcome measurement programs should be adopted by a Maryland program of data collection and outcomes assessment. We need to decide whether we will focus on prevention measures, on medical treatment, or cardiac interventional procedures. Several Subcommittee members, including Douglas Wilson, Ph.D. and Peter Horneffer, M.D., said that we should focus our efforts on hospital-based cardiac interventional procedures, as the area where outcomes may be most readily measured, and the results of this analysis shared, in the "best practices" model. Ms. Teresa Kessell suggested that identifying and measuring prevention and outpatient treatment should remain a future goal for quality and outcomes measurement. Dr. Mispireta agreed that, while prevention and medical treatment are both important to understand and to measure, hospital-based procedures are logistically more practical and possible as an immediate focus, and also agreed with Ms. Barbara Epke's observation that a procedure-based approach lends itself to a valid and credible means of data collection.

Having noted the group's consensus around the measurement and analysis of hospital-based interventional procedures, Dr. Mispireta asked the group to consider which procedures to propose as the initial focus of data collection and reporting. It is also of primary importance to identify, and not to duplicate, the information already being collected. Ms. Susan Glover urged the need to identify the intended audience for the data collected and how it will be used: this in turn will help to determine the nature and scope of the data to be gathered.

4. Presentation: Overview of Selected Quality Improvement Initiatives

Ms. Barclay directed the Subcommittee's attention to a summary handout subtitled "Overview of Topics," which further categorizes some of the choices and decisions within each of the broader questions posed by the Advisory Committee. Within a quality and outcomes database focused on surgery, for example, should the focus be on surgery to address coronary, valvular, or congenital defects? Should catheterizations and other interventions be included? Dr. Mispireta suggested that a focus on coronary and valve surgeries and at least one outcome in cardiac interventions would be a formidable task, but a good start.

Some members questioned the level of specificity sought by the Advisory Committee, or by the Commission, and whether there was any predetermined purpose for a quality and outcomes measurement program. Ms. McLean responded by reiterating the genesis and the goal of the entire Advisory Committee initiative: to generate better data on which to base future State Health Plans and regulatory decisions. The Subcommittee has the option of recommending that

any database developed as a result of the Advisory Committee's recommendations be private, and not available publicly, as is the Commission's Hospital Performance Evaluation Guide. She emphasized that the cardiovascular quality and outcomes measurement was intended to be and to remain separate from the Commission's web-based Performance Evaluation report.

Ms. Barclay reminded the Subcommittee that its task was to design a Maryland model, by learning from and adapting useful and applicable elements of programs from other states. The Subcommittee may decide to invite speakers from other states in its efforts to understand the existing programs and decide the scope, emphasis, and purpose of Maryland's program. Several members reiterated the importance of knowing, as a point of departure, what data reporting and benchmarking requirements are already required of Maryland hospitals with cardiac surgery and therapeutic catheterization programs.

Ms. Alejo reminded the Subcommittee of the importance of keeping its focus on the purpose of the data collection effort: to set up a system in which we can identify problem areas, and determine how best to address them. Dr. Horneffer questioned the inclusion of valvular procedures, as opposed to procedures related to treatment of acute myocardial infarctions; Ms. Kessell agreed, since AMI patients are likely to need future cardiac interventions. In general, the Subcommittee's discussion illustrated how much discussion and deliberation will be required, once it reaches a consensus on its answer to each of the Advisory Committee's questions, to fill in the details. This is particularly true of questions such how a data collection and reporting system will be funded, and how it will be used.

Given the magnitude of the Subcommittee's task, Dr. Mispireta asked that Staff determine what data is now collected, and through which survey instruments, from the State's existing hospitals with cardiac surgery and therapeutic interventional programs. Ms. Barclay proposed to survey the hospitals with cardiac surgery programs, on their participation in the STS survey or other data collection efforts. She said staff would draft a survey for review by Subcommittee members prior to forwarding it to hospitals.

5. Future Meeting Schedule

Ms. Barclay will poll the members by e-mail, to schedule a July meeting, and determine the best dates for meetings in the fall.

6. Other Business

There was no other business discussed by the Subcommittee.

7. Adjournment

Dr. Mispireta declared the meeting adjourned at approximately 7:30 p.m..

Summary of the Meeting
of the
Quality Measurement and Data Reporting Subcommittee,
Advisory Committee on Outcome Assessment in Cardiovascular Care

July 31, 2002
Conference Rooms 108-109, Metro Executive Building
4201 Patterson Avenue, Baltimore, Maryland 21215

Subcommittee Members Present
Luis Mispireta, M.D., Chairman
Diane Alejo
William A. Baumgartner, M.D.
James Brown, M.D.
Barbara Epke
Mercedes K.C. Dullum, M.D.
Susan L. Glover
Peter Horneffer, M.D.
Sanjiv Lakhanpal, M.D.
David Lowry
Cheryl Lunnen
John New
Susheel Sharma, M.D.
Karen Sweeney, RN, BSN
Douglas H. Wilson, Ph.D.
Daniel Woronow, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands

Subcommittee Members Absent
Teresa Kessell, RN

1. Call to Order

Dr. Mispireta called the meeting to order at 6:10 p.m.

2. Approval of Minutes of the June 6, 2002 Meeting

Dr. Mispireta called for a motion to approve the minutes from the Subcommittee's initial meeting, held on June 6, 2002. Dr. Baumgartner moved approval, Dr. Wilson seconded his motion, and the Subcommittee approved the June 6, 2002 minutes as written.

3. Update on Advisory Committee Activities

Pamela Barclay, Deputy Director of the Commission's Health Resources Division, informed the Subcommittee that, at all meetings of the four Advisory Committee subcommittees,

staff will provide a brief update on the work of the other subcommittees, and that all members will receive copies of the other subcommittees' minutes. Staff is currently polling members to schedule meetings for the remainder of this year, and will send a master schedule of all four subcommittee meetings to all subcommittee members. This represents the most practical way to keep members connected to the whole range of ongoing work, given the scope and time commitment of the overall work of the four subcommittees, and the overlap among them of several key issues under discussion.

Ms. Barclay briefed the Subcommittee on the July 25, 2002 meeting of the Long Term Issues Subcommittee, at which its chairman Dr. Passamani led a discussion, intended to identify focus areas for its report to the Advisory Committee. The scheduled speaker, Dr. Diane Becker of the School of Hygiene and Public Health of The Johns Hopkins University, could not attend; her discussion of racial and other disparities in cardiac care will be rescheduled. Ms. Barclay also noted that the initial meeting of the Subcommittee on Inter-Hospital Transport was scheduled for August 22nd at the Commission's offices, and that the initial meeting of the Interventional Cardiology subcommittee would take place at the BWI Marriott on September 4, 2002.

4. Review and Discussion of Draft Survey of Hospital Cardiac Data Systems

As introduction to the Subcommittee's examination of the draft survey form to be sent to existing cardiac surgery programs, discussed at the last meeting as a means of understanding each program's current data reporting and outcomes assessment process, Dr. Mispireta updated Subcommittee members on his efforts since that meeting to develop a consensus among the directors of the State's cardiac surgery programs. In a conference call held on July 29th that included all directors except Dr. Baumgartner of Johns Hopkins, with whom he spoke afterward, Dr. Mispireta sought their views on two major issues: first, the most effective and appropriate kind of database for improving outcomes, and, second, the best means of organizing and implementing a statewide collection and analysis of data on cardiac surgery procedures.

With regard to the first question, the cardiac surgery directors agreed that the most useful model is one focused on quality assurance. To accomplish this, the directors favored the creation of a consortium that would involve all of the cardiac surgery programs, and a representative from the Maryland Health Care Commission, whose activities would be supported by an ongoing workgroup to include representatives of the programs, as well as representation by cardiologists, anesthesiologists, and skilled statistical analysts. This workgroup – whose membership, terms, and required representation would have to be established at the outset -- would have the permanent charge to review data and outcomes, to create initiatives for quality improvement and monitor their results, and, if a program is identified as an outlier in terms of its outcomes, to determine if a site visit is needed, and to prescribe whatever improvement initiatives or corrective actions should be undertaken by that cardiac surgery program.

With regard to the data now collected by the surgery programs, Dr. Mispireta noted that all are collecting elements of the STS data set, although not all programs are collecting the same elements in the same way: of particular significance is the fact that some programs are retrieving data from medical records, rather than at the point of service, as STS requires. This lack of

uniformity in the methods, scope, and use of data collected on cardiac surgery outcomes in Maryland programs would, of course, change once the consortium was established.

Dr. Mispireta noted that the program directors were not sure how best to manage the data collected, whether in-house or outsourced, and suggested that the Subcommittee could learn from presentations by and discussions with Dr. Nugent, of the Northern New England Cardiac Study Group, which manages its data collection and analysis in-house; and Dr. Peterson of the Duke Research Institute, which manages data collection activities for The Society of Thoracic Surgeons (STS) data base.

Dr. Mispireta also observed that some states are moving to mandate the participation in the STS survey by their cardiac surgery programs, and that Maryland might well decide to move in that direction as well. STS provides a distinct set of advantages. It is a well-established database, with well-known elements, and can provide significant experience and both national and regional benchmarks for comparisons. Its risk adjustment framework includes a range of variables that have proven useful as benchmarking measures, as opposed to the predictive function emphasized by some sets of risk adjustment factors. Its software is relatively simple, the institutions themselves can run it, and it provides a vocabulary and set of measures useful in discussions with patients.

Dr. Wilson observed that most of the severity adjustment frameworks currently in use are statistical and linear in nature, while the newest systems, in various stages of research and development, use far more sensitive technologies employing neural networks and artificial intelligence. Consequently, he suggested, the Subcommittee may want to examine these newest models, to determine if Maryland should be among the vanguard of states considering this cutting-edge technology. Dr. Mispireta agreed that there would be significant interest in exploring these new models, among the cardiac surgery directors. Ms. Glover suggested that Med-AI, the Orlando-based company pioneering these new models, could be contacted, as a resource for the Subcommittee.

Dr. Mispireta summarized the teleconference discussion about what elements should be included in Maryland's outcomes evaluation system: while STS collects 250 elements, other institutions collect many more. The Subcommittee should consider whether, if it recommends the adoption of the STS model, it should recommend that it be augmented by additional elements. It will be important for the Subcommittee to hear from Doctors Nugent and Peterson before deciding this point. The directors also discussed the crucial issue of the resources necessary to establish and support the data consortium.

To initiate comments and discussion by the Subcommittee on the approach outlined in the teleconference of cardiac surgery directors, Dr. Mispireta proposed the creation of a workgroup, as an extension of the Subcommittee, to examine further the details and implications of the data consortium model for evaluating outcomes of cardiac surgery in Maryland. Dr. Dullum seconded this proposal, and it received the assent of the Subcommittee. Dr. Mispireta re-emphasized the importance of hearing from Dr. Nugent and other key figures in similar efforts in other states, and Ms. Barclay noted a tentative date of October 2, 2002 for Dr. Nugent's appearance before the Subcommittee.

Dr. Mispireta also pointed out the need to discuss the legal implications of any data collection efforts that Maryland would eventually undertake. Commission Executive Director Barbara McLean noted that the Commission and its counsel have been examining legal issues around patient safety and other data-driven State initiatives involving the collection of adverse-outcome situations, and have determined that, analogous to medical review committees, the specific, individually identifiable data involved in those efforts would be considered "not discoverable." Ms. McLean said that the Commission would expect the same conclusion with regard to collection and analysis of data related to cardiac surgery and cardiovascular disease treatment and outcomes.

The next step, Dr. Mispireta observed, is to determine how to approach data collection and analysis of non-surgical cardiovascular procedures. He asked the Subcommittee, particularly its cardiologist members, to comment on whether an approach similar to that outlined by the cardiac surgery directors would be appropriate to follow for cardiovascular treatment and outcomes. Dr. Wilson suggested that, if angioplasty were to be included, the data elements prescribed by the American College of Cardiology should be used. He observed that only three hospitals in the State now use this survey system, and that a set of data elements or measures as widely accepted and used as STS is for cardiac surgery does not yet exist in cardiology. This, Dr. Wilson suggested, is a concern; data collection related to cardiology tends to be the province of cardiology groups, and therefore closely held as proprietary information. Dr. Sharma added that while standardized data collection on cardiology procedures is increasing, it is not yet widespread, and that a concern exists that technicians, not physicians, are currently collecting what data is being gathered. Dr. Mispireta emphasized that part of the mandate of the Subcommittee is to include interventional cardiology in its deliberations on a Maryland system for collecting and analyzing outcome data in cardiovascular procures. Dr. Sharma suggested that, of the 150 core elements in the ACC database, perhaps we could begin with "eight to ten" clinical measures, for use in comparing hospital performance in this area.

Dr. Mispireta suggested that the Subcommittee's cardiologist members give further consideration to this issue, so as to be able to advise the group. Ms. Lunnen observed that omitting angioplasty from the proposed data collection and evaluation process would be unfortunate, since more advances are being made in that area now than in open heart surgery, and the work of the Subcommittee and its parent Advisory Committee gives Maryland the opportunity to establish a comprehensive standard for data collection and outcomes analysis, with the ultimate goal of improving the quality of care.

Dr. Sharma noted his agreement with the charge to include interventional cardiology in quality measurement efforts, but he observed that any data collection instrument in cardiology intended for physicians to complete had to be "physician-friendly." Dr. Mispireta responded that the ACC requires physicians to complete its survey instrument, and that doing so should be the physician's responsibility. Ms. Barclay suggested that the Subcommittee could compare the ACC's data elements to those collected by New York, Northern New England, and other states' instruments, to see if there is a core of key elements for measuring cardiology outcomes that a Maryland system could include. Dr. Baumgartner observed that the ACC database is already well established, and that creating a new one would be expensive. Dr. Mispireta re-emphasized

the Subcommittee's responsibility to recommend a course of action in its assigned areas of study, to the Advisory Committee, for its final report; he suggested that the directors of cardiology services across the state be contacted, so that a parallel workgroup to that approved for cardiac surgery could begin to work intensively on the Subcommittee's eventual recommendations related to cardiology procedures.

5. Review of Draft Subcommittee Report Outline

Dr. Mispireta asked for Subcommittee comment on a draft outline of the Subcommittee's report, previously provided to members. Subcommittee members had no questions or comments on the proposed report outline at this time.

6. Future Meeting Schedule

Ms. Barclay reminded the Subcommittee members that Staff will contact them regarding future meeting dates, with the intent to set dates for the next several meetings, and to confirm dates for the speakers and resource persons that the Subcommittee has identified.

7. Other Business

There was no other business.

8. Adjournment

Dr. Mispireta declared the meeting adjourned at approximately 7:10 p.m.

Summary of the Meeting
of the
Quality Measurement and Data Reporting Subcommittee
Advisory Committee on Outcome Assessment in Cardiovascular Care

September 17, 2002
Conference Rooms 108-109, Metro Executive Building
4201 Patterson Avenue, Baltimore, Maryland 21215

Subcommittee Members Present
Luis Mispireta, M.D., Chairman
Diane Alejo
Mercedes K.C. Dullum, M.D.
Barbara Epke
Susan L. Glover
Peter Horneffer, M.D.
Teresa Kessell, RN
Sanjiv Lakhanpal, M.D.
Cheryl Lunnen
John New
Karen Sweeney, RN, BSN
Douglas H. Wilson, Ph.D.
Daniel Woronow, M.D.

Subcommittee Members Absent
William A. Baumgartner, M.D.
James Brown, M.D.
David Lowry

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands

Advisory Committee and
Other Subcommittee Members Present
James Scheuer, M.D., Chairman,
Advisory Committee (via teleconference)
Roy Leiboff, M.D., Subcommittee on
Interventional Cardiology

1. Call to Order

Dr. Mispireta called the meeting to order at 6:35 p.m.

2. Approval of Minutes of Subcommittee Meeting, July 31, 2002

Dr. Mispireta moved approval of the minutes from the Subcommittee's meeting of July 31, 2002. Dr. Horneffer seconded his motion, and, after it was established that a quorum was present, the Subcommittee voted to approve the minutes of the July 31st meeting.

3. Update on Advisory Committee Activities

Pamela Barclay, Deputy Director of the Commission's Health Resources Division, briefed the Subcommittee on the meetings and activities of the three other Subcommittees, and announced that the next Quality Measurement and Data Reporting Subcommittee meeting would

be a joint meeting with the Advisory Committee, to be held on October 2, 2002 from 5:30 to 7:30 p.m. at the BWI Marriott in Linthicum. Dr. William Nugent of the Dartmouth-Hitchcock Medical Center will give a presentation on the Northern New England Cardiovascular Disease Study Group's data collection and quality improvement activities. Ms. Barclay noted that all Advisory Committee and subcommittee members have received a master schedule of all meeting dates, which will be updated as subsequent meetings area scheduled.

4. Presentation on The Society of Thoracic Surgeons National Adult Cardiac Surgery Data Base and Outcomes Program

Dr. Mispireta suggested that, in the interest of giving the evening's two speakers ample time for their presentations, the Subcommittee should hold any extensive discussion until after the presentations. He introduced Dr. Eric Peterson, Director of Cardiovascular Outcomes and Quality at Duke University Medical Center, to describe the data collection and outcomes assessment activities of the Society of Thoracic Surgeons (STS) and its National Adult Cardiac Surgery Data Base and Outcomes Program. Dr. Peterson touched on the genesis of the STS data collection and analysis activities in 1990, as a response to the first public release of coronary artery bypass graft mortality data. During the first six years of its data collection effort, STS established its standard data elements and definitions, and, using a single software vendor, expanded to 500 collection sites. At that point, a degree of "stagnation" set in, because the sole vendor had no incentive to continually improve the collection instrument or expand its services. STS opened the software market and uncoupled the data warehouse and analysis functions, which has encouraged continuous evaluation and improvement of the survey since that time.

The STS survey has sought to provide "efficient acquisition" of high quality data, and to improve its value to its members by providing feedback – on a national scale – and by pursuing specific research requested by individual regions or members. STS has sought to improve the timeliness and frequency of its reporting to members, moving from annual to semi-annual reports, and focusing on improving the quality of the data reported to individual sites, which includes data by site and region as well as from the entire national STS membership, and now includes information on best practices. Dr. Peterson noted that STS also continually monitors the quality and completeness of the data its members submit: its data has steadily improved in both areas, and an ongoing process of validating STS data against Medicare data has so far shown "no systematic under-reporting," and no signs of "skimming cases" to skew overall outcomes.

In its development of risk assessment models, STS has the incomparable advantage of being able to "put 1.5 million records to good use." The size of its database provides STS with a sound basis for its prediction models related to mortality, complications, and post-operative length of stay. These models are national in scope, Dr. Peterson observed, because the regional records are not yet extensive enough to provide the same degree of accuracy in prediction of these variables.

STS members have expressed interest from the beginning in obtaining "personalized" reports about the performance of their cardiac surgery programs as compared to their peers, on both the regional and state levels. STS has developed an increasing number of regional reports at

the request of its members, although it remains firmly convinced that the real power and utility of its database, as a tool for peer review and quality improvement as well as for research, lies in its national reach. Dr. Peterson pointed out that while important quality improvement work can be informed by comparisons at the local and regional levels, the national scope and extent of its database provides the most reliable benchmarks and best-practice information.

Dr. Peterson briefly described several states' models for data collection and analysis, as experience from which Maryland could benefit in determining its own path in that direction. Minnesota's cardiac surgeons developed their own data collection entity, to circumvent the state's involvement, but have pursued successful "round robin" patterns of sharing information and quality improvement measures. Massachusetts has mandated that cardiovascular programs submit data to both the STS and the American College of Cardiology surveys, through an independent organization. Iowa set up a collaboration with its peer review organization, which has assisted in both validation of data and quality improvement activities; Colorado's effort began as a collaboration with its PRO, but is evolving toward a surgeon-operated model. Each state's model began with answers to the same kinds of questions under consideration by this Subcommittee: will survey data, once collected at the institution level, be shared, and if so, with whom – other programs and surgeons, the public, the State? The important thing, Dr. Peterson said, was that all of the models developed in response to these basic questions "are compatible with a national organization" like STS.

Dr. Peterson concluded his presentation by noting some recent efforts by STS to "expand the scope" of its work, through research collaborations with the Agency for Health Research and Quality (AHRQ) and the Food and Drug Administration, as well as through the use of its membership as a clinical trials network.

Dr. Horneffer raised a concern, touched on by the Subcommittee in its discussions so far, about the ability to ensure the quality of data submitted to STS and other surveys. Dr. Peterson acknowledged this concern, which STS shares; STS is engaged in validating the completeness and accuracy of its data through comparison to Medicare data, and he suggested that state-level data collection groups might use other claims-based databases in the same way, to audit their survey data.

Ms. Kessell asked Dr. Peterson how STS compensates, in analyses that draw longitudinal comparisons, for changes in the definition of its data elements. Dr. Peterson responded that this issue is the source of considerable debate within STS, reflecting its desire both for consistency over time, and also for innovation and continuous improvement. STS has resolved this dilemma by deciding to "change its definitions when that makes sense, and then analyze the difference that definitional change makes" in the data reported. As a participant in the ongoing work by STS to standardize its definitions as well as their interpretation, Ms. Alejo added that the group of data managers in which she participates has developed a "frequently asked questions" list, and is working on a training manual.

Dr. Mispireta asked Dr. Peterson whether an effort to improve the quality of data collected is more effective if undertaken at the point of entry, or in a subsequent review and correction of the individual medical record. Dr. Peterson responded that accuracy and

completeness at the point of entry is probably more important, but that data checks are important at both points in the survey process; programs seem to be moving toward an emphasis on the quality of data collection at point of service. Dr. Horneffer concluded this discussion by observing that the "real life" demands on staff charged with information entry at the time of surgery make a system of validation of central importance, and Ms. Alejo emphasized the role that data managers and auditors play in that process.

5. Presentation on The American College of Cardiology National Cardiovascular Data Registry

Dr. Ralph Brindis, Chief of Cardiac Services at San Francisco Kaiser Hospital, began his presentation to the Subcommittee by observing that there is considerable overlap between the STS survey and that of the ACC, the National Cardiovascular Data Registry, reflecting the collaboration between the two professional societies. Dr. Brindis explained that the ACC established its data registry in response to "increasing demands to objectively assess process and outcomes of care"; to identify and explain variations in practice and outcomes; to foster quality improvement; to respond to a "profusion" of data reporting requirements, from states, JCAHO, and THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS); and to address the absence of standardization in the data being collected about cardiovascular treatment.

Dr. Brindis described the goal of the ACC's involvement in measuring quality of care in the treatment of cardiovascular disease as "behavior change": examining and analyzing outcomes, and reporting results, leads to changes in the behavior of hospitals, physicians, and systems, and potentially can change patient/consumer behavior as well.

For data measurement to change behavior most effectively, Dr. Brindis said, such an effort must be relevant, credible, and timely. One flaw with New York's system, for example, is the time between treatment episodes and when they are reported: really good, reliable data from 1995 through 1997 was just reported in 2001.

Dr. Brindis described briefly how the ACC-NCDR works, as a one-to-one relationship in which the participant submits confidential data directly to the ACC, through a choice of vendors using certified software. Benefits to members derive from the quarterly submission of data and receipt of reports, an annual ACC users conference on quality, the availability of training materials and clinical/technical ACC staff support, and the linkage of data collected to ACC's guidelines and performance measures.

The version of the ACC-NCDR survey currently in use focuses on collects 142 core elements, is "mapped to other cardiovascular data sets," such as the STS survey and those of New York and Northern New England, and is linked to ACC/American Heart Association guidelines related to acute myocardial infarction, unstable angina, and percutaneous cardiovascular intervention (PCI). The survey process allows for an optional six-month PCI follow-up, to augment case data with vital status and, if expired, primary cause of death, and with the reason for any readmission.

Dr. Brindis characterized the ways in which the ACC monitors and seeks to improve the quality of data collected, with regard to its completeness, consistency, and accuracy. The ACC-NCDR feeds back inconsistencies in data submissions to the reporting program, requires facilities to respond to outlier data, and is currently reviewing programs for on-site auditing that it expects to implement in 2003-2004. To be included in the NCDR's national averages, all elements must be 95-100% reported by at least 85% of the participating institutions. The NCDR began four years ago in November; to date it has enrolled 360 facilities, which have reported on more than 850,000 admissions. ACC-Quarterly reports to members from the Registry contain an executive summary, with comparisons of data to national, state, and regional benchmarks, and a detail section presenting and analyzing a range of variables, events, and outcomes, including demographics, history and risk factors, procedural indications and findings, clinical outcomes, and risk-adjusted PCI mortality.

Dr. Brindis described one of the research projects based upon the Registry's data as potentially quite relevant to the work of the Subcommittee on Interventional Cardiology. A study of "Emergency Bypass Surgery After PCI Failure" has added to the ongoing debate over whether co-location of a cardiac surgery program with a PCI program is "still necessary," although it concluded that "some form of surgical stand-by during PCI is still the standard of care." Dr. Brindis suggested that access to a database of the nature and size of the ACC-NCDR provides the best means of addressing questions such as those under consideration by the interventional cardiology subcommittee.

Dr. Brindis also observed that the ACC's data registry is not "static," and outlined some of the additional measurements and data elements being developed for the next version of the NCDR survey instrument, as well as a Web-based "Cath Lab Toolkit" to support the establishment of a "quality-based" cath lab.

Dr. Dullum asked Dr. Brindis if ACC's survey uses unique patient identifiers, which would enable both longitudinal studies of patient receiving PCI, as well as offer the potential to follow patients into the STS surgery database. Dr. Brindis noted the significant challenge that HIPAA regulations present to any effort to capture admissions of the same patient to additional hospitals, and consequently to any effort to study subsequent PCI or surgical procedures required by a patient over time.

Dr. Woronow asked Dr. Brindis to comment on strategies related to improving the accuracy and completeness of angiographic data, since adverse outcomes "may be subject to interpretation." Dr. Brindis observed that different definitions of clinical success could be addressed at the institutional level. Ms. Kessell asked if there was a way, within the NCDR, to assign cost figures to individual cases, and to collect this data through the Registry; she wondered if Maryland's unique hospital rate-setting system might complicate such an effort. Dr. Peterson noted, in response, that there is "remarkable" variability in where costs are assigned, and without standard definitions, cost analysis is even more difficult.

Dr. Mispireta asked Dr. Peterson to comment what a Maryland-based data consortium could do with STS feedback, particularly the possibility of obtaining specialized reports based on STS data. Dr. Peterson observed that considerable effort and experience have already been

brought to bear on developing and refining the definitions and reports generated by STS, and suggested that Maryland try to develop a system that permitted comparisons with a national database, and takes advantage of existing quality improvement models. Dr. Mispireta asked about the possibility, if Maryland chooses to participate in both the STS and the ACC data collection programs, of obtaining quarterly reports from STS, as it would from ACC. Dr. Peterson replied that data could be reported on a quarterly basis by STS, if it were also collected on that basis. Dr. Mispireta observed that such flexibility and timeliness would be of great importance, in investigating an outcome or event of high variability or high incidence, where we would want information quickly, from Maryland centers only. Flexibility in shaping special-purpose reports would be necessary, in order for any Maryland data collection and outcomes assessment effort to be able to identify emerging problems at the State level, and craft quality improvement measures to address them.

Commission Executive Director Barbara McLean asked if STS and ACC are working with CMS, which has stated its intention to develop quality indicators in coronary artery bypass graft surgery. Dr. Peterson replied that STS is in discussion with CMS, which he characterized as interested in "simple" measures based on claims and volumes. Both STS and ACC will continue to be involved in the development of the CMS measures.

Subcommittee members continued to express concerns about the limitations on longitudinal studies of patient outcomes, given the restrictions of HIPAA's privacy rules on data sharing between institutions. Dr. Peterson suggested that members for whom this is of particular interest should consider attending an upcoming STS conference, where a session will focus on how to comply with HIPAA rules related to patient privacy and still use data for effective quality improvement and research.

Mr. New observed that the Maryland Institute for Emergency Services Systems (MIEMSS) collects trauma data from its nine designated trauma centers throughout the State, and wondered if it would be possible to predict outcomes from pre-hospital condition, such as the presence of shock, as well as age and other underlying conditions. Dr. Peterson noted that both databases present unequaled opportunities for research questions of this nature. Dr. Horneffer wondered why, given the advantages and benefits outlined in the two presentations, an institution would not want to participate, and specifically, if the "cost factor" acted as a deterrent. Dr. Peterson responded that the cost of STS membership was "a couple thousand" dollars per year, with costs of customized reports dependent upon their design and scope; collecting data at the institutional level, if facilities use the existing reporting format, is "cost-effective." Costs will also vary according to where and how data is stored. This decision may affect the degree to which the confidentiality of the data – and of the analyses and actions based upon the data – may be protected.

Dr. Wilson noted a "bias" in the Subcommittee toward proceeding to develop a Maryland data collection and outcomes assessment program, and wondered whether, given "the heightened consciousness for patient safety, and what CMS do," we might be "ahead of the curve." Would the federal effort supersede those of individual states, or yield to them? Dr. Peterson responded that, in his view, Maryland is "doing the right thing at the right time," and positioning the state to be a leader in quality improvement activities. Ms. McLean observed that if CMS mandates

public reporting of Medicare outcomes data, a well-established Maryland program would have to be recognized; Dr. Peterson contended that CMS will likely use an STS- or ACC-based data system, even if it reports different elements in different ways.

6. Other Business

There was no other business.

7. Adjournment

After thanking both presenters, Dr. Mispireta declared the meeting adjourned at approximately 8:35 p.m.

Summary of the Meeting
of the
Cardiac Surgery Data Work Group
Quality Measurement and Data Reporting Subcommittee
September 19, 2002
BWI Marriott, Baltimore, Maryland

Work Group Members Present
Luis Mispireta, M.D., Chairman
James Brown, M.D.
John Laschinger, M.D.
Daniel Woronow, M.D.

Work Group Members Absent
William A. Baumgartner, M.D.
Mercedes K.C. Dullum, M.D.
Peter Horneffer, M.D.
Sanjiv Lakhanpal, M.D.
Anjum Qazi, M.D.
James Todd, M.D.

Commission Staff Present
Barbara G. McLean
Bridget Glazebrook
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands

Commission Counsel
Joel Tornari, Assistant Attorney General

1. Call to Order

Dr. Mispireta called the meeting to order at 6:30 p.m.

2. Presentation on Legal Issues Related to Outcomes Data Collection and Use

Assistant Attorney General Joel Tornari, Commission Counsel, gave a brief presentation on the legal issues that could arise regarding the collection, analysis, and uses of data related to cardiac surgery outcomes. The degree to which the collected data would be able to remain confidential, and used solely for peer review and quality improvement, depends upon how the Work Group chooses to structure the fundamental elements of a data collection effort: the authority under which the data would be collected, and the disposition and control of the data. With regard to the authority for the data collection, Mr. Tornari explained that a purely voluntary effort undertaken by the cardiac surgery programs would require no legislative or regulatory action by the State. However, maintaining the confidentiality of the data becomes more complicated if the Work Group or the Subcommittee should decide to mandate submission of outcomes data, and an enforcement mechanism is needed, or if some or all of the data would be shared with a State agency. In that case, the Maryland Public Information Act and other concerns become a factor.

With regard to the disposition and control of the collected data, and particularly where it is housed, the degree of involvement of a State agency is also the key factor. If the State has custody of the data, or if the data is voluntarily shared with the State, it is subject to requests for disclosure under the Public Information Act. If, alternatively, the data collection is voluntary, and shared only by a consortium of private users, the collected data is not subject to requests under the Public Information Act. The data might, however, be subject to civil discovery in certain legal proceedings, such as medical malpractice lawsuits.

It is true, Mr. Tornari observed, that if the State had custody of outcomes data comprised of patient-specific elements of hospital medical records, these are generally protected from discovery under the Act, except that a State agency has discretion to permit access to such data for research purposes. For example, the Commission administers access to its databases for research projects, which must appropriately protect the confidentiality of the data, and demonstrate that the release is in the public interest, through its Institutional Review Board (IRB.) Confidential, patient-specific information held under the State's control may be obtained by law enforcement agencies, and through discovery in certain civil proceedings.

Mr. Tornari observed that the way to structure an outcomes data collection effort of this nature that provides the highest degree of confidentiality and non-discoverability is through the statutory model for medical review committee, which during the 2002 session was clarified and recodified as Health-Occupations Article §§1-401 and 14-501, Annotated Code of Maryland. The Work Group and the Subcommittee could structure the model they recommend to the Advisory Committee so as to conform to the existing statute, or seek a change in the law that encompasses the design for data collection, analysis, and custody ultimately agreed upon. In the medical review committee model for peer review and quality improvement, the Department of Health and Mental Hygiene and accreditation agencies may obtain data, but are prohibited from re-releasing it.

Following Mr. Tornari's overview of the legal framework in which the Work Group needs to consider the model it will recommend, and for the benefit of Dr. John Laschinger, a member of the Work Group who has not participated in the Subcommittee's deliberations to date, Dr. Mispireta summarized the discussions and presentations to date on this subject. These have included a teleconference (with follow-up briefings of those unable to participate in the conference call) of medical directors of Maryland cardiac surgery programs, and the Subcommittee's meeting held two days ago, on September 17, 2002, at which the group heard presentations by Dr. Eric Peterson on behalf of the Society of Thoracic Surgeons (STS) Cardiac Surgery Data Base and Outcomes Program, and by Dr. Ralph Brindis, for the American College of Cardiology's National Cardiovascular Data Registry.

Dr. Mispireta characterized the consensus of the surgeons' group as in favor of using the STS database, a "national data base that has to comply with medical records privacy laws," particularly since the cardiac surgery programs already use its survey

instrument in some form or degree. The consensus is that this database should be used for peer review, to identify problem areas and aggressively address them, and should have its repository elsewhere, though where has not been determined. This data consortium would be managed by a steering group, much like the Work Group, which would review the operation, evaluate problems, and propose innovations or special reports as needed.

Dr. Mispireta suggested that a possible way in which this effort could begin is through the State's mandating participation by the cardiac surgery programs in the STS database, after which the group would function independently, with an annual report to the Commission. Mr. Tornari asked about the level of detail envisioned for such a report; Dr. Mispireta said that the report could characterize the year's work by the consortium and the steering group, describe the particular outcome or other focus of the year's analysis and quality improvement efforts, and perhaps outline in an aggregated summary any changes in that particular measurement over the reporting period.

In that model, Mr. Tornari observed, a Public Information Act request could request the report, but would not have access to any underlying data, or to details of specific quality improvement steps that the consortium or its steering group had taken. He also observed that using a "quasi-public" model for a data repository – one mandated by statute but independent of most State requirements, such as the Maryland Health Care Foundation – would potentially provide a similar level of protection against discovery of underlying details of process and outcome.

Dr. Laschinger asked if any part of the data consortium's report, to the Commission or to its members, could be discovered; Mr. Tornari responded that, if the body was to be included within the statutory variations on the medical review committee model, in existing language or through a new provision, that these underlying data and details were not likely to be discoverable.

Dr. Mispireta observed that all of the cardiac surgery medical directors and their institutions (and the Subcommittee, of course) are wrestling with the funding necessary to undertake this effort. Although each institution is already collecting some of the STS data elements, there would be an additional cost for full participation and for managing the data. If State funding were used to offset any of this cost, that level of involvement could potentially subject the database to a higher degree of discoverability. This would not be the case, Mr. Tornari observed, if the data consortium and its operations were defined under the medical review committee statute; in general, if State funding took the form of a "seed money" grant, and not of a contract with attendant obligations, the independence of the consortium and its confidentiality protections would probably remain intact.

Dr. Woronow observed that, once a State consortium would submit data to STS, by definition it would go "beyond Maryland," and he wondered if that fact would increase its discoverability within the State. Mr. Tornari responded that it was possible that the submission of data to STS would have that effect, particularly since STS itself is

not a medical review committee. Dr. Woronow noted that the Subcommittee's presenters at Tuesday evening's meetings presented lists of research publications based on STS and ACC data, but thought that such data was highly aggregated in the course of describing and explaining findings from the detailed national and regional data. Still, perhaps the underlying data on which such research is based might be discoverable.

Commission Executive Director Barbara McLean noted that two or three bills currently before Congress would protect confidentiality of medical information collected and analyzed solely for purposes of improving quality of care and patient outcomes. Again, to access that kind of protection, an entity will have to fit within the definition of a medical review committee; Mr. Tornari suggested that the safest way to accomplish that would be to try to design a consortium to fit within the several entities enumerated in the current Maryland medical review committee statute. The Commission will introduce legislation next session to ensure medical review committee status, and the resulting level of confidentiality, for data collected and analyzed by a Patient Safety Center, to be established pursuant to 2002 legislation.

Dr. Mispireta requested that Mr. Tornari provide the Work Group with the list of entities defined as a "medical review committee" under current statute, to help it determine if the cardiac surgery data consortium under consideration conforms to any existing model under that framework. Mr. Tornari will supply that list, and the applicable statute, to the Work Group and its outside legal counsel, perhaps in-house counsel of the involved institutions, to use in their deliberations.

Dr. Mispireta reiterated the consensus of the cardiac surgery directors' group that an independent group whose data is privately maintained probably represents the best way to protect the privacy, and therefore the acceptability and the effectiveness, of a cardiac surgery consortium whose purpose is peer review with a goal of improving quality of care and outcomes. The lesson of tonight's legal briefing, he said, is that any group created as a result of the Subcommittee's eventual recommendations must fit the medical review committee model, to enjoy the highest level of confidentiality. Ms. McLean reminded Dr. Mispireta and the Work Group members that, if a statutory change is needed to achieve that status for a cardiac surgery data consortium, the rationale for denying the public's access to the data must be clearly and forcefully articulated; she suggested that one way to elicit support in that context might be to propose a requirement of regular, independent audits of the data, as a way of ensuring the quality and reliability of the data, and the consistency and accuracy of its collection.

Dr. Brown voiced some remaining concerns about some of the models currently under discussion, wondering if the Northern New England model – though more expensive because limited in size – did not afford a greater degree of confidentiality, and therefore both a higher level of trust and of "open, honest" discussions of problem outcomes or programs, and effective remedies. Dr. Mispireta noted that the final form of a Maryland data consortium is far from decided, and that the State has not limited the Subcommittee to any particular model. Dr. Brown hoped that Maryland will steer away from the New York and Pennsylvania models using a "report card" approach, since that

model lends itself to the manipulation of aggregate outcomes by diverting the high-risk patients: the effect in which "New York achieves lower overall mortality" but that of the Cleveland Clinic goes up, from the difficult cases being exported. Dr. Mispireta responded that research has shown that the New York model did not change patient migration as such.

Dr. Laschinger sought to clarify that the Commission "wants us to be involved," and to create the quality-oriented data consortium under discussion, whether voluntary or not. Ms. McLean related the group's work, and that of the Subcommittee, to a recommendation in the most recent State Health Plan governing cardiac surgery and interventional cardiology that led to the establishment of the Advisory Committee and its four subcommittees, and their charge to bring recommendations in the identified areas to the Commission. This is not a "mandate," but certainly indicates the Commission's view that Maryland could and should take a leadership role in this area. She noted that there is start-up funding in next fiscal year's Commission budget, which could help begin the consortium, but no funding for its ongoing operation. The Commission will continue to address issues such as equity of access to cardiac surgery and interventional procedures, and volume-quality evidence in its planning and regulatory activities.

Dolores Sands, Chief of Specialized Services in the Commission's Health Resources division, expanded upon the Plan's rationale for proposing the Advisory Committee on Outcomes Assessment, as a means of going beyond the Plan's central quality principle – the evidence-based link between volume and quality – to develop "better, more sensitive" indicators. She observed that the federal Centers for Medicare and Medicaid Services (CMS) is moving to include cardiac surgery and interventional cardiology procedures in its planned public reporting of data on the performance of hospitals. Ms. McLean added that, if the CMS approach to web-based nursing home outcomes reporting is any indication, the hospital-based reporting program will also select the simplest elements. The challenge for CMS will be to move beyond claims-based data, to avoid telling an oversimplified, potentially misleading story. It may well become even more important, she observed, to have Maryland's own data collection and outcomes improvement program up and operating. Dr. Mispireta suggested that a "cooperative effort" and relationship between any eventual data consortium and the Commission was very important, understanding that the exact nature and extent of the relationship would be shaped by the confidentiality issue.

Dr. Brown said that two key questions remained to be addressed: where to house the data collected, and the "form and content of the report to the Commission." A third, Dr. Mispireta added, was the structure of the entity, and how it conforms to the medical review committee model. The Subcommittee has heard presentations on the STS and ACC programs, and on October 2, 2002 at a joint meeting with the Advisory Committee, will hear from Dr. William Nugent about the Northern New England model. The repository of the data, as long as it is not the State, could be an independent Maryland entity in the Northern New England mold, or one of the national organizations, Dr. Mispireta observed. Since the cardiac surgery group favors the STS elements and

approach, what will remain is to go through basically the same deliberative process with regard to cardiology procedures.

With regard to the process for reaching consensus on the entire scope of its charge, Dr. Mispireta noted that, after the October 2nd presentation, the Subcommittee will have the information it needs to decide on the model it will propose to the Advisory Committee, and through the Advisory Committee to the Commission. The Work Group must, therefore, meet – whether by teleconference or, preferably, in person – and reach a decision related to the cardiac surgery portion of the recommendation.

Dr. Mispireta asked that each member of the Work Group discuss with his or her hospital the likely direction of the group's recommendations, so that each institution understands the implications of an independent data consortium, especially regarding how the entity will be funded. Some support already exists, at the hospital level, in the collection of selected STS elements; to this would be added: the cost of joining STS; of collecting all of the elements on a quarterly basis, and requesting quarterly, not semi-annual, reports from STS; of supporting the work of an ongoing steering group; and the additional cost of any special reports the group would request. Dr. Mispireta noted his intention to contact Dr. Peterson, to get cost estimates for the kind of special report typically requested by STS members, and to give that information to Work Group members as soon as possible, for their discussions with their institutions.

Dr. Brown expressed the need to encourage and articulate, in discussions with the hospitals, a positive view of this data consortium and quality improvement effort, and its benefits, in order to ensure the highest level of active participation and the best results. Dr. Mispireta noted his intention to update the other members of the Work Group via teleconference as soon as possible, and to invite them to Dr. Nugent's presentation at the Subcommittee's joint meeting with the Advisory Committee on October 2, 2002. The group needs to meet during the second or third week in October, in order to finalize its recommendations and convey them to the Subcommittee at a November meeting, which has not yet been scheduled. Commission Staff will contact members about a meeting date.

3. Review of Survey Results

Presentation of the survey results was postponed.

4. Adjournment

Dr. Mispireta declared the Work Group adjourned at 7:30 p.m.

Summary of the Meeting
of the
Cardiac Surgery Data Work Group
Quality Measurement and Data Reporting Subcommittee

November 26, 2002

Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, Maryland

Work Group Members Present
Luis Mispireta, M.D., Chairman
James Brown, M.D.
Peter Horneffer, M.D.
Sanjiv Lakhanpal, M.D.
Daniel Woronow, M.D.

Commission Staff Present
Barbara G. McLean
Pam Barclay
Colleen Lates
Susan Panek
Debbie Rajca
Dolores Sands

Work Group Members Absent
William A. Baumgartner, M.D.
Mercedes K.C. Dullum, M.D.
John Laschinger, M.D.
Anjum Qazi, M.D.
James Todd, M.D.

Guests Present
Vanessa Purnell, MedStar Health

Quality Measurement and Data Reporting Subcommittee Members Present
Diane Alejo, R.N.

1. Call to Order

Luis Mispireta, M.D., Chairman of the Cardiac Surgery Data Work Group, called the meeting to order at 6:25 p.m.

2. Update on Advisory Committee Activities

Dr. Mispireta asked Pam Barclay to update the Work Group on activities of the Advisory Committee on Outcome Assessment in Cardiovascular Care. Ms. Barclay noted that the Long Term Issues Subcommittee had met on November 20, 2002 to begin discussing their final recommendations to the full Steering Committee. The Long Term Issues Subcommittee will meet again on December 12, 2002 for a background briefing on cardiovascular disease in underserved populations. The Quality Measurement and Data Reporting Subcommittee will meet on Wednesday, December 11, 2002 to consider the recommendations from the Cardiac Surgery Work Group. The Interventional Cardiology

Subcommittee is scheduled to meet again on Monday, December 23, 2002; a meeting of the Inter-Hospital Transport Subcommittee is being scheduled for January 2003. Ms. Barclay noted that the full Steering Committee would meet on December 17, 2002 to begin reviewing the status of subcommittee recommendations.

3. Draft Recommendations from the Cardiac Surgery Data Work Group on the Design of a Maryland Quality Improvement Initiative for Cardiac Surgery

Dr. Mispireta distributed a table outlining options for designing a Maryland quality improvement initiative for cardiac surgery services (Attachment 1). The table outlined key components of a quality improvement program, including: scope; data elements; data management strategy; organizational structure and governance; submission of data; access to data; and funding. After reviewing and discussing options for each element, it was the consensus of the Work Group to recommend the following approach to the full Quality Measurement and Data Reporting Subcommittee:

Scope	•CABG Procedures •Valve Procedures
Data Elements	•*Core Data Set*: STS Adult Cardiac Surgery Database •*Supplemental Data Set*: Identified by Maryland programs based on research and process analysis requirements
Data Management Strategy	•Use the Duke Clinical Research Institute (DCRI) independent of STS to process and manage data
Organizational Structure and Governance	•Structure as independent consortium contracting with participating hospitals to perform medical review committee function under existing state law (potential for MHCC to be ex-officio member)
Submission of Data	•Start with voluntary reporting and assess compliance
Access to Data	•Under medical review statute, proceeding records and files re confidential and not discoverable or admissible in evidence •Require aggregate report to MHCC annually
Funding	•Hospitals •Grants

4. Adjournment

Dr. Mispireta adjourned the Work Group meeting at 7:30 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care
Interventional Cardiology Subcommittee

September 4, 2002
BWI Airport Marriott Hotel
1743 West Nursery Road, Baltimore, Maryland 21240

Committee Members Present

David O. Williams, M.D., Chairman
Robert R. Bass, M.D.
George Bittar, M.D.
Sridhur Chatrathi, M.D.
Charles Cummings, M.D.
Michael Fiocco, M.D.
Candice Fonke, R.N.
Scott Friedman, M.D.
Frank Gravino, M.D.
Bartley Griffith, M.D.
William Herzog, M.D.
Roy Leiboff, M.D.
Keith M. Lindgren, M.D.
Steve B. Lowenthal, M.D.
Catherine L. Monge
Robin P. Newhouse, R.N.
Hilary T. O'Herlihy, M.D.
Stephen H. Pollock, M.D.
Bernard Rubin, M.D.
Mitchell Schwartz, M.D.
Dominic Seraphin
Karen Stair

Committee Members Absent

James L. Field, Ph.D.
Mark Midei, M.D.
James Porterfield, M.D.
Sidney Smith, M.D.

Members of the Public Present

Lucy Ferko, St. Joseph Medical Center
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Gary Jones, Shore Hospital System of Maryland
Martha Nathanson, Lifebridge Health
Jack Neil, Anne Arundel Medical Center

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

1. Call to Order and Introductions

David O. Williams, M.D., Chairman of the Interventional Cardiology Subcommittee, called the meeting to order at 3:00 p.m. Members of the Interventional Cardiology Subcommittee and Maryland Health Care Commission staff introduced themselves.

2. Overview and Background

In his introductory remarks, Dr. Williams said that he was the Director of the Cardiovascular Laboratory and Interventional Cardiology at Rhode Island Hospital. He said that the issues to be considered by the Interventional Cardiology Subcommittee were important for patients, hospitals, and physicians throughout Maryland. Dr. Williams noted that it was likely that the Subcommittee would be getting inquiries from other states regarding its discussions. He also stated that answering questions posed in the subcommittee charge would be a difficult task and that debate among Subcommittee members were expected. Dr. Williams concluded this remarks by outlining how the subcommittee would function in taking positions on issues.

Dr. Williams asked Ms. Pamela Barclay, Deputy Director for Health Resources, to provide an overview of the Commission. Ms. Barclay thanked the Subcommittee members for taking time from their busy professional and personal lives to participate in advising the Commission on issues relating to interventional cardiology services. Then Ms. Barclay provided a brief overview and description of the activities and programs of the Commission. The presentation provided the history of the Steering Committee and its four Subcommittees (Quality Measurement and Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport). According to Ms. Barclay, the charge to the Interventional Cardiology Subcommittee includes the following issues:

1. Should State health planning policy be modified to permit hospitals to perform primary angioplasty without the requirement for on-site cardiac surgery?

- How do outcomes of primary angioplasty performed in hospitals without on-site cardiac surgery compare with outcomes in hospitals with on-site surgery?
- What institutional resources are required for a primary angioplasty program?
- What are the program development requirements for a primary angioplasty program?
- Is there a relationship between volume of primary angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
- What process and outcome measures should be used for on-going quality assessment?
- Which patient groups are suitable for primary angioplasty in settings without on-site cardiac surgery?

2. Should State health planning policy be modified to permit hospitals to perform elective angioplasty without the requirement for on-site cardiac surgery?

- Is there evidence that current policy restricts availability of elective angioplasty services to Maryland patients?
- How do outcomes of elective angioplasty performed in hospitals without on-site cardiac surgery compare with the outcomes of elective angioplasty performed in hospitals with cardiac surgery?
- Should the Commission consider a pilot project study to assess whether it would be appropriate to modify current policy regarding the availability of on-site cardiac surgery backup for certain groups of elective angioplasty patients?
- How should this pilot project be designed and implemented? What would be the resource and program development requirements for a participating hospital?
- What process and outcome measures should be used for on-going quality assessment?
- Is there a relationship between volume of elective angioplasty procedures and outcomes? If so, is there a minimum volume of cases that should be performed annually?
- Which patient groups would be suitable for inclusion in a pilot program study of elective angioplasty?

3. Discussion of the Subcommittee Charge, Structure, and Timetable

Dr. Williams asked if any of the Subcommittee members had questions. Keith Lindgren, M.D. asked who maintains C-PORT registry data. Ms. Barclay replied that Tom Aversano, M.D. at Johns Hopkins Hospital maintained the C-PORT registry. Dr. Williams said that Dr. Aversano, could be invited to advise the Subcommittee about the the C-PORT project.

Hilary T. O'Herlihy. M.D. raised the issue of having members from other states involved in deliberating Maryland's policies governing interventional cardiology services. Ms. Barclay responded that she understood Dr. O'Herlihy's position, but noted that the inclusion of other state representatives was a way of adding expertise to the discussions. Stephen H. Pollock, M.D. commented that including representatives from other states was a good idea and a way to minimize institutional bias in discussing issues.

Charles Cummings, M.D. asked how many hospitals in Maryland perform angioplasty. He suggested that the Subcommittee consider collecting data from existing programs on the characteristics and outcomes of angioplasty procedures. Dr. Williams recommended that a document be developed to summarize scientific information that is available concerning angioplasty procedures. He said that he had talked with Chris Cannon, M.D. in Massachusetts about developing that type of "state of the evidence" white paper for the subcommittee. Dr. Williams noted that a similar document was helpful to Rhode Island. He added that American College of Cardiology guidelines should also be made available to be subcommittee. Dominic Seraphin stated that there was also a need for information on a range of issues, including transportation, geographic location (metropolitan versus rural area), cost, and personnel.

Dr. Williams agreed and said there are subgroups of patients as well as subgroups of environments that should be considered by the subcommittee. Regarding C-PORT, he noted that Dr. Aversano could possibly share the lessons learned from the C-PORT project regarding operational issues with the subcommittee. Dr. Pollock recommended that inter-hospital transport issues be considered and noted several Baltimore area hospitals were beginning to track information regarding arrival at the hospital, arrival at the cath lab, and outcomes for primary angioplasty patients. He said that this data should be available to be subcommittee by December 2002. Dr. Pollock said he was also a member of the Inter-Hospital Transport Subcommittee and the information he gathers would be shared with that subcommittee as well as the Interventional Cardiology Subcommittee.

Dr. Williams commented that it might be a good idea to include inter-hospital transport as well as emergency medical services (EMS) protocol considerations in the subcommittee discussion. Scott Friedman, M.D. said that travel distances were important to consider in weighing options for planning primary angioplasty services. Mitchell Schwartz, M.D. agreed and said the cost impact of driving had to be considered. Dr. Cummings mentioned that overlap is important since helicopters are not always available to transport patients between hospitals.

Bernard Rubin, M.D. asked about the quality of care implications if a patient were taken to a hospital that does not offer angioplasty? Dr. Williams replied that the service could be considered like trauma. Robert R. Bass, M.D. said that the trauma system is voluntary, but there are certain protocols. The overwhelming majority of trauma patients in Maryland receive care in a trauma center. According to Dr. Bass, regulations regarding trauma centers are already in place and it would not be difficult to add another type of service to the regulations.

Dr. Schwartz asked about the cost. He said the cost would different in Baltimore when compared to Hagerstown. Dr. Bass stated that with respect to trauma, volume makes a significant difference in outcome. Dr. Williams then asked the subcommittee if there were additional questions that should be added other than regionality and EMS. Dr. Cummings said that overall costs needed to be considered. He asked how much the costs would be and how much equipment would be needed if the Subcommittee said that C-PORT is a standard of care and should be offered by every hospital. Dr. Schwartz stated there might not be enough staff. He asked if anyone was dealing with the topic of staff and Ms. Barclay replied that staffing was not a specific topic that was assigned to any one subcommittee.

Dr. Friedman commented that a patient receives thrombolytics because primary angioplasty may be unavailable many times. Dr. Williams said this relates to the volume issues and he suggested that staff organize available information on myocardial infarction prevalence in Maryland. Dr. Williams noted there is a plan underway in Boston to have EMS only go to the hospital with angioplasty. This plan will be monitored. Eighty to ninety percent of the time the service has to be provided. Dr. Williams said the process

and outcome measures noted in the subcommittee charge would tie into the work of the Quality Measurement and Data Reporting Subcommittee.

Frank Gravino, M.D. stated if hospitals do not have a team available at night it would be difficult to consider the service dedicated to 24/7 availability. In metropolitan areas, it is easy to get experienced cardiologists, but in regions with no open heart programs, it is often difficult to get qualified staff. Dr. Williams stated that physician requirements should be considered and that support staff is also an important operational issue. Roy Leiboff, M.D. urged the subcommittee to look at cost issues. The cost analysis has to be compared to saving one life vs. the cost of other interventions. Dr. Pollock said that the focus should be on what is best for patient care.

George Bittar, M.D. asked if a hospital participated in C-PORT and met time frames whether there would be a way to track the service use 24-hours a day. Dr. Pollock commented there was a difference in having C-PORT and using it. Dr. Cummings said that thrombolytics could also be tracked. He also commented on the concept of an on-call team to go where there are more AMI's than physicians on call.

Dr. Pollock stated the subcommittee had a responsibility to assure that people in Maryland get the same coverage regardless of where they live. The State should treat cardiac patients like trauma patients. Dr. Cummings said there is a problem rotating an experienced interventionist for 50 MI's a year. There are not enough to hire and wait for MI's to occur. Dr. Pollock said his facility has two interventionists on duty every weekend. Bartley Griffith, M.D. stressed the importance of considering regionality in the deliberations.

Dr. Bass said there had been early anxiety about community hospitals and hospitals without trauma centers. Early consideration of primary angioplasty will result in a similar stigma. Dr. Pollock commented that patients want to get to the hospital as quickly as possible and they should have access to care. Dr. Rubin mentioned there is a link between primary angioplasty and elective angioplasty and the Subcommittee should discuss defects in various areas. When angioplasty is performed in a center, additional backup might be required. Dr. Griffith asked, "Are we to think there won't be an increase in surgery centers?" Ms. Barclay said projections are identified in the State Health Plan through 2002, which will be updated during 2003. She noted that available trend data does not show substantial increases in the volume of open heart surgery cases.

Dr. Lindgren stated that the Subcommittee had to look at outcomes. Are the results of C-PORT without cardiac surgery backup comparable to hospitals with cardiac surgery backup? Dr. Friedman pointed out that in Baltimore City there were multiple programs within close proximity. On the other hand, in more rural areas it can take considerable time to find a hospital willing to take a patient and then transfer that patient.

Dr. Williams said there are a lot of questions about C-PORT. He said he hoped the Subcommittee has a presentation from Tom Aversano, M.D. at the next meeting.

4. Future Meeting Schedule

Dr. Williams stated that the Interventional Cardiology Subcommittee would meet again around in early October and that staff would poll members to find the best date.

5. Other Business

There was no other business.

6. Adjournment

The meeting adjourned at 4:50 p.m.

Summary of the Meeting of the
Advisory Committee on Outcome Assessment in Cardiovascular Care
Long Term Issues Subcommittee

June 5, 2002
Conference Room 110, Metro Executive Building, 4201 Patterson Avenue,
Baltimore, Maryland 21215

Subcommittee Members Present
Eugene R. Passamani, M.D., Chairman
Patricia Casals
Donald H. Dembo, M.D.
Sheila Druck, R.N., BSN
Aaron Kenigsberg, M.D.
George Moran, M.D.
Lisa Myers, R.N., M.S.
John M. Ryan, M.D.
Cheryl VanKuren

Subcommittee Members Absent
Jane R. Apson, M.S.P.H., Ph.D.
Irene Buadoo, M.D.
Lynn Frank, F.A.C.H.E.
Kenneth Rempher, R.N.

Members of the Public Present
Andrew G. Cohen, Consultant
Angelyn B. Estwick, Master of Public Health Candidate, George Washington University
Vanessa Purnell, MedStar Health

Guest Speakers
Jeanette Jenkins, Director, Office of Health Policy, Community Health Administration, DHMH
Edward K. Kasper, M.D., Associate Professor of Medicine, Director, Cardiomyopathy and Heart Transplant Service, Johns Hopkins School of Medicine
Thomas Aversano, M.D., Cardiologist, Johns Hopkins School of Medicine

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

1. Call to Order and Introductions

Eugene Passamani, M.D., Chairman of the Long Term Issues Subcommittee, called the meeting to order at 6:00 p.m. Members of the Long Term Issues Subcommittee, guest speakers, and Commission staff introduced themselves.

2. Overview and Background

Dr. Passamani asked Barbara G. McLean, Executive Director of the Maryland Health Care Commission, to provide an overview of the Commission. Ms. McLean thanked the subcommittee members and guest speakers for taking time from their busy professional and personal lives to participate in generating discussions relating to long term care issues. Then Ms. McLean provided a brief overview and description of the

activities and programs of the Commission. Ms. McLean also stated that the four Subcommittees (Quality Measurement and Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport) would discuss ideas for future direction and relay their recommendations and proposals to the Steering Committee for consideration.

Ms. Jenkins questioned if there were plans to merge the four separate Subcommittees into the Steering Committee. Ms. McLean responded that each Subcommittee Chairman is a link to the Steering Committee. In this capacity, the Chairman may directly report each Subcommittee's activities to the Steering Committee, thereby reducing the need for all members to spend their valuable time attending additional meetings. Ms. Barclay added that at least one member on a Subcommittee was a member of the Steering Committee. In the case of the Long Term Issues Subcommittee, Donald Dembo, M.D. is a dual participant in addition to Dr. Passamani.

Dr. Passamani asked Pamela W. Barclay, Deputy Director for Health Resources, to provide an overview of the goals of the Advisory Committee and how it relates to the Subcommittee on Long Term Issues. Ms. Barclay distributed an organizational chart that illustrated the four primary focus areas of the Long Term Issues Subcommittee. These areas include Access, Health Status, Research, and Health System Organization. The activities in these areas should be considered "work in progress" that may be modified over time. According to Ms. Barclay, the four subcommittees have many interconnections. It is the function of the Steering Committee to work with the four separate subcommittees and connect them by identifying strategies toward reaching overall goals. Ms. Barclay explained that while the time frame for the Advisory Committee is ambitious, it is achievable. The Advisory Committee is expected to submit an initial report to the Commission over the summer. A final report is due to the Commission by January 1, 2003.

Aaron Kenigsberg, M.D. questioned if any figures had been considered regarding the cost of medicines. He stated that there might be an interest in getting people in Maryland on lower cost drugs, such as generic prescriptions. Dr. Passamani said he did not recall that drug costs had been a topic of discussion. However, Dr. Passamani said the Subcommittee could discuss this issue, as well as any other matters pertaining to cardiac care. According to Dr. Passamani, the Subcommittee should consider if there are other areas in patient care that should be placed higher on the agenda. He said that congestive heart failure is just one area that is to be considered.

Dr. Dembo asked if other organizations in the State were examining the same patient care areas. He suggested that the Subcommittee should communicate with other organizations so that there is no duplication of studies being made.

Ms. McLean explained that Delmarva is currently collecting data on the Commission's behalf and that staff is in daily contact with that agency. Plans are also being made to announce meetings of the all Subcommittees in the public hearing

schedule to increase awareness of the Commission's work in the area of cardiovascular care.

3. Presentation: Healthy Maryland Project 2010 – Options for Cardiovascular Disease Assessment/Target Setting

Ms. Jeannette Jenkins presented the goals of the Healthy Maryland Project 2010 with respect to Cardiovascular Disease. She advised that much of her information was downloaded from the Healthy People 2010 website which is located at http://mdpublichealth.org. Ms. Jenkins said that the previous goals of Healthy People projects had been to reduce or control health problems. Under the 2010 project, the primary goal is to eliminate health disparities and increase quality and years of health life. Healthy People 2010 is a comprehensive set of national health objectives for a ten-year period. These objectives are developed by a collaborative process and are designed to measure progress over time. According to Ms. Jenkins, there are 10 Leading Health Indicators (LHI) that reflect the major public health concerns in the United States. These indicators are: (1) physical activity, (2) overweight and obesity, (3) tobacco use, (4) substance abuse, (5) responsible sexual behavior, (6) mental health, (7) injury and violence, (8) environmental quality, (9) immunization, and (10) access to health care. The second indicator, overweight and obesity, closely relates to the subject area of cardiovascular disease since overweight individuals are often affected with heart disease.

Ms. Jenkins stated that the Health Maryland Project 2010 contains a Health Improvement Plan (HIP) that includes statewide modules as well as local modules. Consequently, this ongoing report concentrates the efforts of both state and local health departments, and the appendices provide a linkage between their findings. Ms. Jenkins pointed out that research has always been conducted on a "shoestring budget," however; LHI's should still be measurable down to the local level.

Related objectives from other focus areas indicate that there is overlap in other health areas where heart disease and stroke are considered. For example, persons with chronic kidney failure often suffer from cardiovascular disease. Healthy People 2010 examines objectives for improving these health issues. Ms. Jenkins stated that the 2010 data are age adjusted to the 2000 standard population. This objective differs from Healthy People 2000 that adjusted the death rates using the 1940 standard population.

Ms. Jenkins described the Healthy People 2010 "Toolkit" that sets out the vision, goals, objectives, baselines, and targets that are used by participants during the planning process. She stated that it was important that objectives be measurable. Additionally, continuity and comparability are vital in reaching the goals of Healthy People 2010.

Andy Cohen asked how each county selected a priority area to examine. Ms. Jenkins said that several counties conducted their own research. Healthy People 2010 allowed local health departments to choose one priority at first, but this method did not work because each county tended to select infant mortality. Since variety was needed, other priorities were recommended and subsequently chosen.

Thomas Aversano, M.D. questioned how the baseline for coronary heart disease deaths went from 200 to 160. Ms. Jenkins replied that various factors, such as different behaviors, were considered. Healthy People 2010's Heart Disease and Stroke section (12-1) provides information regarding reducing coronary heart disease deaths. In 1998, the baseline for coronary heart disease deaths was 208 while the 2010 target is 166.

4. Presentation: Heart Failure

Edward Kasper, M.D. presented a profile of the compelling problem of heart failure in the United States. He said that heart failure is a common pathway for other medical problems. Data show that 4.8 million people have heart failure in the United States. Of these diagnoses, 60 percent are due to coronary heart disease. Each year, between 400,000 and 700,000 new cases of heart failure are diagnosed. During the same period**,** 250,000 people die of heart failure. The number of heart transplants per year is approximately 4,000. Of those individuals hospitalized with heart failure, 80 percent are older than 65 years. As a result, more Medicare dollars are spent for heart failure than for any other diagnosis. In addition, $500 million is spent annually on drugs related to heart failure.

According to Dr. Kasper, the "Rule of Halves" and "Second Rule of Halves" can best illustrate statistics relating to heart failure. The Rule of Halves shows that one-half of patients are treated, but have no heart failure. Another quarter of patients have heart failure and diastolic left ventricular dysfunction (LVD) while the final quarter of patients have heart failure and systolic LVD. Regarding the Second Rule of Halves, one-half of patients have few or no symptoms of heart failure, while one quarter has heart failure, and the remaining quarter has heart failure and receives the appropriate therapy. Although 30 percent of patients exhibit diastolic dysfunction, 70 percent of patients show signs of systolic dysfunction.

Dr. Kasper discussed the marked change in phenotype, including increased adrenergic activity. In his analogy, Dr. Kasper pointed out that the key concept of change was the "remodeling" of the left ventricle from an "ellipse" shape to a "beach ball" shape. Also, it has been demonstrated that ACE inhibitors reduce mortality in moderate and severe heart failure. Dr. Kasper said there had been a host of trials regarding various beta-blockers, however, it was still difficult to treat patients with heart failure. Certain drugs, such as diuretics, are used in conjunction with heart medications for the management of such medical conditions as edema. By controlling accompanying medical problems, critical patients are often kept out of the hospital. Digoxin has been shown to have no affect on mortality; however, it improves functional capacity and decreases hospitalization rates. REMATCH is a device that is used in very sick patients. Studies show that there is a 48 percent reduction in the risk of death in patients given LVAD when the REMATCH device is used. Improved quality of life is also noticed when the device is used.

Different countries have heart failure compliance guidelines. In the United States regarding LVEF, it is common to see that 70 percent of patients have ejection fraction measured at some point in their care. Data indicate that most patients with systolic dysfunction should be on ACE inhibitors. In addition, hospital readmission rates suggest that improvements could be made in the quality of care patients are receiving.

Dr. Kasper discussed a study that was conducted regarding 200 patients who were at high risk for hospital readmission for heart failure. The patients were randomized to multidisciplinary care or usual care for a six-month intervention at two clinical sites, Bayview and Johns Hopkins. The results of the project showed there were 43 chronic heart failure (CHF) hospitalizations and 7 deaths in the intervention group. There were 59 CHF hospitalizations and 13 deaths in the usual care group. Both quality of life and quality of care improved with intervention. The cost was approximately the same in 1998 dollars.

There are some problems associated with intervention care. For example, nurse practitioners can only follow 30 to 50 heart failure patients, and it is sometimes difficult obtain physician cooperation. Additionally, not all patients need such an expensive intervention and funding is also an issue. Comorbidities also become critical in this patient population.

A Tele-Watch System was then discussed. This is a computerized system of follow-up care in which patients call into the system on a daily basis and are asked approximately ten varied, simple questions. Information is graphically displayed and there are modules for heart failure, diabetes, and COPD. The system is currently being tested within the Johns Hopkins system.

Dr. Kasper concluded his presentation by summarizing the problems associated with heart failure. He said that heart failure is a disease of the elderly and is growing because our population is aging. Treatment for heart failure is also complex and at times difficult to administer. Additionally, it is often difficult to prove benefit in a large cohort using a disease management approach. Dr. Kasper stated that randomizing patients is an important method for studying how to improve quality care for heart failure patients.

Dr. Passamani commented that the State of Maryland had a very good data system. He asked if there was a technology transfer system, or a means whereby the State would look into and reconnect with a pilot system. Dr. Kasper responded that he would be happy to look at the data. He also said he envisioned a multi-center approach with much support, one that would report the findings of 2,000 patients instead of only 200.

Dr. Dembo stated that no money was saved in this project. He said the problem is that under the current system of care, patients are not benefiting from the best there is available. If we had an organized method of following patients who were not terminally ill, the system would be improved. Dr. Kasper explained that the data in his presentation pertained to mostly Class 3 patients. He also said that we needed to pinpoint the costs

correctly the next time. Dr. Kasper added that nurse practitioners were very well trained in treating heart failure patients.

5. Presentation - Heart Failure: Patient Outcomes Clinical Trial

Dr. Aversano presented information concerning his concept for a prospective, randomized comparison of usual care with multidisciplinary disease management for heart failure patients. He said that this Heart Failure Patient Outcomes Clinical Trial study could be very important in terms of understanding heart failure. According to Aversano, three areas should be considered when studying the care of heart failure patients: (1) assurance of quality, (2) access to care, and (3) containment of cost. In his view, there is now a poor track record concerning quality of care for heart failure patients.

The Commission can take several steps to promote better quality of care. These measures include: (1) supporting the concept of a patient outcomes trial relating to heart failure, (2) creating a necessary regulatory environment to allow studies to proceed, (3) becoming a "co-investigator," (4) assisting researchers in getting the attention of the Centers for Medicare and Medicaid Services (CMS), and (5) promoting the concept to the Maryland healthcare community. There are several factors that help to make Maryland a good area to implement these measures. For instance, cooperative ties already exist through systems like the Cardiovascular Patient Outcomes Research Trial (C-PORT) project. Also, because Maryland is a small state geographically, it is easier to obtain assistance in gathering data. In addition to having two major medical centers with clinical experts in the field of health failure, Medicare is located within the state.

Disease management, particularly regarding a chronic disease such as heart failure, can be a sensible approach to improving treatment. Currently, heart disease is extremely costly to the healthcare system and there are multidisciplinary and fragmented approaches to treatment. Disease management can lead to rapid development of new treatment strategies and options. By doing so, patients can be empowered with cognitive, behavioral, measurement, and reporting tools that (1) reduce system demand and cost, (2) increase compliance, and (3) enhance clinical outcomes. Using a disease management system, data is submitted from the patient and/or nurse, but the patient ultimately manages his own disease. Disease management tools such as self-assessment screeners and individualized treatment plans apply to different strata of risks.

The annual cost for a chronically ill patient is approximately $30,000 per year. Disease management could decrease costs and reduce the mortality associated with chronic disease. Regarding heart failure, a usual care vs. intervention study could be conducted comparing patients with mild, moderate, and severe medical conditions. Patients could be followed for a least one year to determine differences regarding medical outcomes, quality of life issues, and economic circumstances. Various technical issues would have to be considered regarding the study such as (1) patient population source, (2) how to identify, randomize, and stratify, (3) guidelines and treatment algorithms, (4) how to apply guidelines, and (5) medical-legal issues. Funding could potentially be

provided by CMS, the Agency for Healthcare Quality and Research, third party payers, and private employers.

According to Dr. Aversano, the study is important because chronic heart failure is increasing in the population at epidemic proportions. Not only does quality of care vary widely among chronic heart failure patients, but outcomes for these patients also vary. Additionally, the economic burden of chronic heart failure is very high. Dr. Aversano concluded that the study would fulfill one of the missions of the Commission by assuring the greatest access to the highest quality care at the lowest cost.

6. Subcommittee Discussion

Dr. Passamani commented that better care might reduce costs related to heart failure. Dr. Aversano agreed and stated that are many underserved patients in Maryland. Fifty percent of the underserved are African Americans and this figure is out of proportion when compared to other races. Dr. Kasper added that rate for underserved African American males was much higher than for white males. According to Dr. Aversano, patients spend much of their time traveling to the offices of their physicians. This time would be decreased through the use of disease management because part of patients' follow-up care would be performed via the telephone.

Dr. Kenigsberg asked if prevention might not be a better method of treating heart disease. He suggested treating patients who were 40 or 50 years of age for problems that lead to heart disease before the problems actually occurred. Dr. Aversano replied that the cost of preventive treatment was high and the cost of heart failure continued to rise.

Dr. Passamani stated that it was difficult to talk to a person who feels healthy about problems that could occur in the future. However, one of the reasons the Subcommittee was formed was to discuss ideas and attempt to find various approaches to reducing heart failure in Maryland.

Dr. Aversano said there has always been a concern about prevention. He provided the example of tobacco company Philip Morris' anti-smoking campaign. Figures revealed that smoking actually increased in spite of the prevention tactics that were taken. Ms. Jenkins commented that it was important how an organization crafts its message. Dr. Kenigsberg added that it was important to educate the State of Maryland about heart failure disease.

George Moran, M.D. mentioned there were high costs involved with end-of-life patients that had to be considered regarding heart failure. If patients receive one high bill for pills or medical visits, they will not return for treatment. He said he did not know how to include this concern in the State Health Plan.

Dr. Dembo commented that Maryland did not do a bad job regarding wellness. He provided the example of offering children shots to prevent diseases. Dr. Dembo said that there were rewards for wellness and punishments for not offering it. It is difficult to

provide preventive measures when comorbidity is involved. Physicians, he said, should become more responsible for prevention of health problems that are related to adults. It is necessary to develop a prevention system for adults like the one that Maryland currently offers to babies and children. Dr. Dembo also suggested that high blood pressure and diabetes should also be considered in connection with heart failure.

Dr. Passamani asked each member to consider the next steps that should be taken and invited everyone to write him a note, in care of Ms. Barclay, responding to the format and issues that were discussed during the meeting. Dr. Passamani also requested that each member select a few items on which to focus during the upcoming report. He said that since the final report was due in January 2003, a preliminary report should be drafted by October 2002. Drs. Kasper and Aversano said they would forward copies of their slide presentations to Ms. Barclay. Dr. Passamani then thanked everyone for participating in the meeting.

7. Future Meeting Schedule

Dr. Passamani said he would like the Subcommittee to meet one more time before August 2002. He requested that members include dates when there were available, as well as topics for presentations, and include this information when they submitted their notes to Ms. Barclay.

8. Other Business

There was no other business.

9. Adjournment

The meeting adjourned at 8:15 p.m.

Summary of the Meeting of the
Advisory Committee on Outcome Assessment in Cardiovascular Care
Subcommittee on Long Term Issues

July 25, 2002
Conference Room 108-109, Metro Executive Building, 4201 Patterson Avenue,
Baltimore, Maryland 21215

Committee Members Present
Eugene R. Passamani, M.D., Chairman
Jerilyn Allen, Ph.D.
Jane R. Apson, M.S.P.H., Ph.D.
Patricia Casals
Donald H. Dembo, M.D.
Sheila Druck, R.N., BSN
Stacey Fisher, M.D.
Lynn Frank, F.A.C.H.E.
Jeanette Jenkins
Aaron Kenigsberg, M.D.
George Moran, M.D.
Lisa Myers, R.N., M.S.
Kenneth Rempher, R.N.
John M. Ryan, M.D.

Commission Staff Present
Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

Committee Members Absent
Irene Buadoo, M.D.
Ruth Maiorana
Cheryl VanKuren

Guests Present
Martha Nathanson, Sinai Hospital

1. Call to Order and Introductions

Eugene Passamani, M.D., Chairman of the Long Term Issues Subcommittee, called the meeting to order at 6:00 p.m. Members of the Long Term Care Subcommittee and Commission staff introduced themselves.

2. Approval of the Previous Minutes (June 5, 2002)

The minutes were approved as submitted.

3. Overview and Background

Pam Barclay provided an update on the Steering Committee as well as updates on the other subcommittees. She explained that the Subcommittee on Long Term Issues would be provided with the minutes of the other subcommittees since all of the subcommittees were interconnected. In particular, the other subcommittees discuss some overlapping, long-range issues that would be of interest to the Subcommittee on Long Term Issues.

According to Ms. Barclay, the Steering Committee is expected to meet in September. A schedule of the Committee's upcoming meetings, as well as minutes from these meetings, will be provided to the Subcommittee on Long Term Issues. Ms. Barclay stated that two distinguished guest speakers, Kenneth I. Shine, M.D., Chairman of the New York State Cardiac Advisory Committee, and James L. Field, Director of the Cardiovascular Roundtable, Advisory Board Company, attended previous Steering Committee meetings and presented useful information regarding challenges and trends in cardiovascular services. Summaries of their presentations are included in the minutes that will be distributed.

On Wednesday, July 31, 2002, the Quality Measurement and Data Reporting Subcommittee is scheduled to meet. Plans are also underway to schedule a joint meeting in early October between the Quality Measurement and Data Reporting Subcommittee and the Steering Committee. It is anticipated that the guest speaker will discuss regional quality improvement efforts in the New England area.

The first meeting of the Inter-Hospital Transport Subcommittee is scheduled for Thursday, August 22, 2002. Likewise, the Interventional Cardiology Subcommittee has not held its first meeting. Ms. Barclay announced that David Williams. M.D., an interventional cardiologist from Rhode Island, has agreed to chair the subcommittee and plans are being made to schedule a date for the first meeting. Dr. Passamani reiterated that all subcommittee members would be receiving copies of all subcommittee minutes in addition to the schedules for all meetings. The meetings are open to the public, and all subcommittee members are encouraged to attend related cardiovascular discussions.

Barbara McLean advised that the meeting schedules would be posted on the Commission's web site and in the legislative hearing schedule.

4. Presentation: Background Material on Cardiovascular Disease in Underserved Populations

Dr. Passamani advised that the guest speaker, Diane Becker, Director, Johns Hopkins Center for Health Promotion, was unable to attend this evening's meeting. However, Dr. Becker has agreed to speak at the next scheduled Long Term Issues Subcommittee meeting.

5. Discussion on Potential Focus Areas

A total of nine letters were received in response to Dr. Passamani's June 5, 2002 request for recommendations concerning potential focus areas related to cardiovascular care. Dr. Passamani explained that the Maryland Health Care Commission and the Steering Committee should be thought of as catalysts in developing methods to reduce cardiovascular disease through process improvement in Maryland. As a starting point for the Long Term Issues Subcommittee's discussion, Dr. Passamani presented a series of criteria that might be of use in selecting areas of focus for the subcommittee. (The model, incorporating the suggestions of the Subcommittee members, is attached.)

Dr. Passamani commented that he had noticed some tension in the nine letters that were received with respect to primary and secondary prevention measures. Ms. Lynn Frank suggested that there were significant disparities that should be noted. Ms. Jeanette Jenkins recommended that prevention be added to the model.

Aaron Kenigsberg, M.D. agreed that prevention should be included. He also stated that pharmaceutical representatives tend to promote expensive drugs when they should be providing samples of less expensive drugs. Dr. Kenigsberg suggested that Maryland could set up organizations that promote providing samples of low cost, generic medications to patients, instead of starting patients on higher-costs drugs. Ms. Barbara McLean noted that CareFirst Blue Cross/Blue Shield was encouraging patients to ask their physicians for generic medications.

Donald Dembo, M.D. stated that the subcommittee needed to consider the resources required for health care. He added that the staff that is required is expensive. Dr. Dembo also said that it was necessary to prioritize how we deal with the limited resources that are available. Dr. Passamani related an incident where several firefighters were killed while fighting a fire because their procedures and approaches no longer fit the problem (Don Berwick's presentation at Johns Hopkins Hospital two years ago). His analogy suggested that perhaps the cardiovascular medicine model needs adjustment. With the state serving as a catalyst, Dr. Passamani suggested that research and education might lead to ideas of how the model could become more focused. Stacey Fisher, M.D. said that the dysmetabolic syndrome population should be added to the model. She added that this medical condition was driven by many factors, including obesity.

Ms. Lisa Myers discussed the public access defibrillation program that is administered by the Maryland Institute of Emergency Medical Services Systems (MIEMSS) under the authority of the Emergency Medical Services Board. Facilities that meet certain criteria are authorized to obtain and maintain automated external defibrillators (AEDs) on-site by appropriately trained non-medical personnel before the arrival of emergency medical services personnel. An authorized facility could be a single organization located at one place or a business that operates at several locations (sites). Currently, there are 177 registered AEDs and 320 sites in Maryland.

Dr. Fisher advised that places such as shopping malls and airports have AEDs. Ms. Myers added that BWI Airport also has AEDs in place. Three lives have been saved due to the use of the defibrillators at BWI Airport.

Dr. Passamani suggested that each subcommittee member express his or her view regarding the model, and suggest ways in which the model could be developed. Dr. Kenneth Rempher stated that good data was needed to support analysis of any disease process. He suggested that the subcommittee compare the current and desired methods.

Dr. Kenigsberg said that aspirin should be prescribed before a stroke occurs. He said a patient could get "more bang for the buck" if a generic drug was used in the early treatment of such a disease. In his opinion, medical providers failed if a patient died at 40 years of age, but did not fail if a patient died at 90. Dr. Passamani commented that asymptomatic individuals at a high risk of heart disease are hard to identify and that it was difficult to get patients who feel well to commit to preventive medicine. Dr. Kenigsberg mentioned that society had changed since the 1950s so perhaps people would be more open to preventive medicine now.

Dr. Moran suggested there was confusion regarding the scope of the Subcommittee. He asked if the subcommittee was looking to generate standards. Dr. Moran also suggested that the subcommittee take the best practices that are known and utilize them better. Dr. Passamani said that perhaps the subcommittee could measure how Maryland compares to the best practices of other states.

Dr. Dembo commented that technological advances were continuing. He said defibulators would probably be on people's wrists by 2005. However, Dr. Dembo said there were disparities concerning the underserved population. Fifteen years ago, there was disparity in access and the disparity continues. He asked how we could get individuals into the system, because that is where the medical community has failed. Dr. Dembo added that we should take advantage of the entities that are available such as churches and barber shops to educate the public.

Ms. Sheila Druck stated that some existing programs had been included in Cheryl VanKuren's follow-up letter to the June 5, 2002 subcommittee meeting. Ms. Druck suggested that the subcommittee should compile the information and determine the best practice. Dr. Passamani commented that communication between a physician and a patient is not the sole method for building support associated with cardiovascular education. A complementary method might also be used. Ms. Patricia Casals suggested that there should be education for the medical and non-medical community.

Ms. Myers suggested that the subcommittee pick one primary and one secondary preventive measure. She said that one is as important as the other. Ms. Myers also stated that AEDs were a step further than CPR. Ms. McLean recommended that the subcommittee consider: (1) what are the funding possibilities, (2) what is the attraction for obtaining a grant, and (3) what are the existing measures (e.g., CHF and stroke).

Dr. Jane Apson stated that she had worked in the community and is aware that diabetes is prevalent in Maryland and continuing to increase. Dr. Apson said that new information would catch the medical community's attention and ultimately help the people at risk. She suggested that the subcommittee share the behavior change model with Diane Becker before the next meeting.

John Ryan, M.D. stated he was an advocate for primary prevention. He said that hypertension was occurring and that if the disease was controlled, it would reduce stroke, CHD, CHF, and, renal failure among others.

Dr. Fisher agreed that the subcommittee should choose one primary and one secondary preventive measure. She said that people in the underserved areas do not know their blood pressure or cholesterol levels. Screening should be available through church groups, shopping malls, schools, and health clubs on a regular basis. Dr. Fisher said there was a 10-15 year period when people do not go to the doctor. Pregnant women tend to receive medical care. Funding could occur through hospitals and drug companies.

Dr. Passamani asked what would happen if a person was diagnosed with a medical condition. Dr. Fisher suggested that the person would be referred to a primary physician or given a list of doctors or clinics.

Dr. Jerilyn Allen mentioned that hypercholosterolemia is not well controlled and should be added. Family history was also a risk factor. Ms. Frank said African Americans and Latinos receive information through churches. Wellness centers are more appropriate for African Americans. Ms. Frank said that we must build access to primary care and that there are many uninsured adults in Maryland. Exercise should be part of the school curriculum.

Ms. Jeanette Jenkins stated that there were health disparities and that gaps need to be closed. She said she was very sensitive to cost and is aware that funding will be limited. Ms. Jenkins suggested that a media partner could be a pilot in generating information about generic drugs.

Dr. Passamani said effectiveness and cost-effectiveness must be considered regarding the best practice. Dr. Dembo commented that the medical community is already aware of risk factors. Therefore, a pilot program is not needed to make the risk factors known. Instead, communication needs to be improved to address health care, cost, morbidity, and mortality.

Dr. Fisher said that many individuals do not take their medications correctly. Additionally, some people cannot afford medications so they fail to visit physicians.

Dr. Passamani stated the subcommittee members had provided good comments and suggested that they go around the table once more in case anyone had additional remarks. Dr. Kenigsberg said that doctors should address the cost-effective manner of

generic drugs. According to Dr. Kenigsberg, use of generic drugs does not result in bad medical care.

Dr. Dembo stated that we spend much money for health care and that money is not always spent wisely. Dr. Passamani commented that if a patient has money and insurance coverage, he has access to excellent care.

Ms. McLean stated that we need to identify external sources of funding for these potential projects. The Commission does not have money available so there would be a need to identify additional sources of money. Ms. Frank said there is money in the health care system. She suggested a tax as an incentive.

Ms. Frank commented that we must consider what the barriers are in the system. One-on-one care with private physicians is very expensive. Other types of providers such as physician's assistants and nurse practitioners should be considered. There are many reasons why it is difficult to obtain patient compliance. For example, regarding obesity, there seems to be something in our culture that leads to it. Additionally, there is availability to food.

Dr. Passamani commented that no one had mentioned cigarette smoking as a primary factor relating to vascular disease. Ms. Apson said that education regarding the dangers of smoking cigarettes would have to occur in schools. Dr. Passamani asked about adding a higher tax to cigarettes. Dr. Fisher stated that cigarettes were already expensive and people continue to purchase them. Dr. Dembo agreed that education would have to begin early, for example, with third-graders. Dr. Passamani said that once individuals are addicted to cigarettes, it is difficult to stop smoking. Dr. Ryan commented that millions of dollars were already being spent on campaigns against cigarette smoking.

Ms. Apson stated that there is a disparity regarding educating individuals living in urban and rural communities.

Dr. Passamani then asked if the subcommittee members had any suggestions regarding speakers or topics for the next meeting. Dr. Dembo mentioned that a prediction for one part of the body, or a total body scan, might identify non-entity diseases.

Dr. Passamani said that, in a broader sense, a person might know about risk the day before that he or she has a heart attack. Dr. Dembo said the subcommittee should consider what is in the research stream and how things might change. Ms. Barclay commented that Jim Field of the Advisory Board is focusing on technology issues with respect to the future organization and delivery of care and that he might be willing to speak to the subcommittee on technology trends.

Dr. Moran stated that we already have a lot of data, for example, histograms for patients who are high risk. He also mention third-party payer "stop" letters. Dr. Moran said that the state could utilize this information to look at behaviors indirectly.

6. Review of Subcommittee Report Outline

Dr. Passamani then asked Ms. Barclay to discuss the draft outline of the Report of the Subcommittee on Long Term Issues. Ms. Barclay said that the outline was a method of getting the group to think about the scope and organization of the report that will be submitted to the Steering Committee. She said it was a working document and would be revised throughout the subcommittee meetings.

Dr. Passamani asked the subcommittee members to review the outline and submit their comments on how to improve it to Ms. Barclay within two weeks. He said the comments did not have to long, and they could be handwritten. Then Dr. Passamani asked if the subcommittee should consider Maryland's rank compared to other states. Ms. Barclay advised that the Heart Association could provide this information. Dr. Dembo said the subcommittee should consider what it could do regarding the rationing of health care.

Ms. Jenkins commented that the subcommittee had mentioned Medicaid and hospitals. She wondered if funding from Medicaid should be considered before the subcommittee started tinkering with other methods. Dr. Passamani suggested that the subcommittee listen to Diane Becker's presentation before reaching a decision.

Ms. Fisher said that Medicaid might not be the right system to consider. She stated that individuals with Medicaid already had access to medical care. The subcommittee should consider those individuals who are caught in-between having private insurance and those with Medicaid--individuals who have nothing.

7. Future Meeting Schedule

In addition to providing comments on refining the outline, Dr. Passamani asked each member to consider the future steps that should be taken regarding the subcommittee's next meeting. He invited everyone to write him a note, in care of Ms. Barclay, responding to the format and issues that were discussed during tonight's meeting. Then Dr. Passamani thanked everyone for participating in the meeting.

8. Other Business

There was no other business discussed by the Subcommittee.

10. Adjournment

The meeting adjourned at 7:30 p.m.

CARDIOVASCULAR DISEASE MODEL

Criteria	Primary Conditions				Secondary Conditions		
	Cigarettes	HBP	Diabetes	Obesity	CHF	SD	Stroke
Common Disorder							
Effective Treatment Available							
Minority/Underutilization							
Evidence of Under Utilization of Treatment							
Easy to Find Patients w/Disorder							
Treatment Complex							
Treatment Costly							
Untreated Mortality							
Untreated Morbidity							
Programs in Place							
Prevention: Simple or Complex							

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care
Subcommittee on Long Term Issues

October 17, 2002
Conference Room 108-109, Metro Executive Building, 4201 Patterson Avenue, Baltimore, Maryland 21215

Committee Members Present

Eugene R. Passamani, M.D., Chairman
Jerilyn Allen, Ph.D.
Jane R. Apson, M.S.P.H., Ph.D.
Irene Buadoo, M.D.
Patricia Casals, R.N.
Sheila Druck, R.N., BSN
Stacey Fisher, M.D.
Ruth Maiorana
George Moran, M.D.
Lisa Myers, R.N., M.S.
Kenneth Rempher, R.N.
John M. Ryan, M.D.

Committee Members Absent

William Balke, M.D.
Donald H. Dembo, M.D.
Lynn Frank, F.A.C.H.E.
Aaron Kenigsberg, M.D.
Cheryl VanKuren

Members of the Public Present

Vanessa Purnell, MedStar Health

Guest Speakers Present

Diane Bild, M.D., Medical Officer
Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

1. Call to Order

Eugene Passamani, M.D., Chairman of the Long Term Issues Subcommittee, called the meeting to order at 6:05 p.m.

2. Approval of Previous Minutes (July 25, 2002)

The minutes of the previous meeting were approved as submitted.

3. Update on Advisory Committee Activities

Pamela W. Barclay provided an update on activities of the Steering Committee as well as other subcommittees. She advised that a joint meeting of the Steering Committee

and the Quality Measurement and Data Reporting Subcommittee was held earlier in the month. During that meeting, William Nugent, M.D. of the Dartmouth-Hitchcock Medical Center presented information regarding the Northern New England Cardiovascular Disease Study Group. Ms. Barclay also stated that the Commission had been provided with an interim progress report at their October meeting. A copy of that report will be forwarded to all subcommittee members in the next few weeks. Another meeting of the Quality Measurement and Data Reporting Subcommittee is being scheduled at the present time.

During the most recent meeting of the Inter-Hospital Transport Subcommittee, presenters provided information regarding inter-hospital transport systems involving the Peninsula Regional Medical Center, MedStar , and Rural Metro. It was agreed that if better information was to be obtained, it would be necessary to standardize data. Ms. Barclay also informed the Subcommittee that the Interventional Cardiology Subcommittee had met on October 16, 2002. During that meeting, Thomas Aversano, M.D. provided a detailed presentation regarding the C-PORT project that provided an overview of the clinical trial phase and the on-going data registry. Dr. Aversano also provided his ideas about future state oversight of primary angioplasty in hospitals without on-site cardiac surgery services.

4. Review of Background Information and Follow-up Discussion on Focus Area Priorities

Dr. Passamani asked John Ryan, M.D. to discuss a series of handouts that he had prepared for Subcommittee members. Dr. Ryan described each of the charts (i.e., Income of Household by State and Stroke Mortality Rate by State) and said that overall, Maryland's figures were in the middle of those of other states.

Then Dr. Passamani suggested that each Subcommittee member consider the progress the Subcommittee had made to date. He asked those present to recall the presentations that were made a few weeks earlier by Drs. Edward Kasper and Thomas Aversano. Dr. Passamani asked each Subcommittee member to state his or her priorities regarding the final recommendations that should be considered.

According to Ms. Sheila Druck, the Subcommittee should focus on a primary condition and a long-term issue. If left with one single choice, Dr. Ryan would select hypertension as an important predictor of heart failure. If allowed two choices, he would include congestive heart failure. Dr. Jerilyn Allen said there are multiple risk factors (i.e., cholesterol with hypertension). Heart failure is the number one reason for hospitalization of the elderly. If Dr. Allen had two choices, she would also select congestive heart failure (CHF) .

Dr. George Moran stated there is a problem with how information is presented. He said that ACE inhibitors must be considered and that patients must take the correct ACE inhibitors at the right dose. He added that to begin policing could cost a lot of money. Dr. Moran agreed with Dr. Ryan's opinion. He also said that diabetes is worth

two risk factors and that it is a major public health issue. There is also an epidemic of obesity that can lead to diabetes. According to Dr. Moran, diabetes leads to infarction, which ultimately leads to heart failure. While Dr. Moran said the MHCC model is not a bad idea, he believes that educating the public should be a high priority.

Dr. Jane Apson stated that there is bias toward primary prevention. She is concerned about the disparity in the geographic and socioeconomic areas in Maryland. Dr. Apson suggested that a program be developed for pharmaceuticals. She mentioned that her mother was in her 80's and did not want to be admitted to an institution. As Dr. Apson considers her mother's health, she believes that the focus should be on primary care physicians because CHF occurs too late.

This was the first meeting that Ms. Ruth Maiorana attended, but she stated that she supported what the previous Subcommittee members had said. She commented that there must be a combination of primary and secondary prevention. Ms. Patricia Casals also said she believed in primary and secondary conditions. She stated that primary prevention should focus on education for obesity. By doing so, diabetes and hypertension will be reduced. As far as secondary prevention, she liked the model grid and commented that there needed to be a balanced approach. She believes that education decreases length of stay and this ultimately reduces the workload of physicians.

As far as primary prevention, Ms. Lisa Myers had no preference. As for secondary prevention, she believes that sudden death should be the focus. Additionally, she said that CHF would have merit. Data should be collected that is specific to Maryland. Mr. Kenneth Rempher stated there is a greater focus on metabolic typing in diabetes. Studies already have been done and we do not want to reinvent the wheel.

Stacey Fisher, M.D. commented that there should be a primary and secondary focus. The primary focus should be metabolic syndrome awareness and obesity. This is a huge contributor to the secondary factor of sudden death. Defibulators are important if they can be used. There should be education programs with one focus point from each group.

Ms. Myers stated that Chicago has implemented a public-access defibrillation program at all of its airports. Defibrillators are strategically located through airport terminals. They are also available at the Baltimore-Washington Airport. The Maryland Institute of Emergency Medical Services Systems (MIEMSS) provides the requirements for participation in its Automated External Defibrillators (AED) Program in its "Information and Application Packet." A business or organization that meets certain requirements may set up a program whereby someone suffering a cardiac arrest on the authorized facility's premises can receive treatment with an AED on-site by appropriately trained non-medical (lay) personnel before the arrival of emergency medical services personnel. Entities exempt from the AED Program include healthcare facilities, federal government agencies, jurisdictional EMS operational programs, and commercial ambulance services. MIEMSS has an epidemiology department that is capable of collecting data regarding locations where heart attacks are occurring. (The home is

actually the primary place where heart attacks occur.) Public awareness of the AED Program is growing, but it needs to reach more people. A report regarding the progress of the AED Program will be submitted to the General Assembly shortly.

According to Ms. Myers, there will be long-term follow-up regarding patients who utilized AEDs. Additionally, public service announcements will occur. It is important to get the physicians involved in the program because facilities need direction. Police departments often get to the scene of a cardiac victim before the Emergency Medical Service (EMS) technicians arrive. A rural grant has also been awarded. Nine jurisdictions in Maryland were designated as rural with a little under $200,000 allotted for AEDs in those communities. EMS will provide the training that will begin by August 31, 2003.

Dr. Apson mentioned that perhaps EMS personnel could be trained to teach lay people on the use of AEDs. Dr. Passamani asked if there was a recommendation that the Subcommittee could make to place AEDs appropriately across the state of Maryland. Ms. Myers stated that in order to do so, data collection should continue and physician involvement should occur. Dr. Passamani suggested that the MHCC should consider getting a legal opinion to clarify some issues. Ms. Myers agreed and said that some insurance providers may not understand state law.

Dr. Moran suggested that it would easier to recruit physicians if a "toolkit" was in place, and if liability issues were clarified. Ms. Myers advised that she had a list of 10 or 12 physicians who would be willing to participate in the AED program. Dr. Passamani commented that communication was a major problem. He referred to a recent *New England Journal of Medicine* paper that reported AED's had successfully resuscitated approximately 10 of 18 people at Chicago airports.

5. Presentation: Detection of Sub-Clinical Coronary Artery Disease

Dr. Passamani introduced Diane Bild, M.D., MPH, Medical Officer in the Division of Epidemiology and Clinical Applications at the National Heart, Lung, and Blood Institute. Dr. Bild stated that the Multi-Ethnic Study of Atherosclerosis (MESA) study had been launched five years ago and involved examining a variety of technologies, including coronary calcium, cardiac MRI, carotid MRI, carotid ultrasound, ECG, arterial wave forms, endothelial function, and ankle-brachial index. Until recently, there had been a "traditional" approach regarding coronary risk assessment, but this has moved toward a more "tiered" approach. Both the American Heart Association (AHA) and the National Cholesterol Education Program (NCEP) recommend more aggressive treatment. However, more information is needed about technologies. Dr. Bild described the NCEP ATP III – 3 Levels of Risk which included: (1) Zero to one risk factor, (2) 2+ risk factors, and (3) CHD and CHD risk equivalents[8].

[8] Risk equivalents include diabetes, peripheral vascular disease, AAA, and symptomatic carotid artery disease.

According to Dr. Bild, there are various types of technologies to detect subclinical atherosclerosis. For example, the electrocardiogram (EKG) has been available for over 100 years. While carotid ultrasound is an easily performed procedure, standardization can be difficult. Dr. Bild stated that Ankle/Brachial BP Index was almost ready for "prime time." Endothelial function testing, while an early indicator of subclinical atherosclerosis, is not yet ready to be utilized on a full-scale basis. EBCT (Electron Beam Computed Tomography)/Cardiac Multi-Slice Computed Tomography (MCT) is on the horizon for use, but more data is needed. Cardiac MRI (stress test with injection) is very expensive. Carotid MRI is capable of examining characteristics of plaque and can be done with or without contrast.

Calcium has been evident on x-rays for years and is a specific marker of atherosclerosis. In the 1980s, an EBCT scan was used, however, since the late 1990s, General Electric (GE) and Siemens have produced multi-detector scanners. Virtually identical results are obtained with both technologies. Additionally, if one scans them more than once, measurements are reproducible. The brightness of calcium is also measurable. The Agatston score demonstrates 40 sections of the heart. Prevalence of coronary calcium in an asymptomatic population shows there is an increase with age. Prevalence is also higher in the male population. The African American race shows coronary calcium rates are much lower than in other races.

The possible clinical values of CAC measurement are: (1) identify high-risk individuals requiring more intensive intervention or diagnostic investigation, (2) rule out (almost) CHD as a cause of chest pain, (3) monitor CAC to follow effects of therapy, and (4) inhibit or encourage calcification. According to Dr. Bild, there is much we do not understand such as, "Is calcium just an "innocent bystander?" She said it might stabilize or destabilize the plaque and we need to determine calcium's role. Dr. Bild stated that it is necessary to monitor the results to understand where the measures fit.

Dr. Passamani asked Dr. Bild if she had any sense of when answers would be available regarding risk assessment. Dr. Bild replied that it would be a few years before the results would be available.

Dr. Apson questioned whether there was a correlation between dietary calcium and coronary calcium. Dr. Bild noted the complex physiology governing serum calcium concentrations and thinks it unlikely that there would be a relationship between dietary calcium and coronary calcium.

6. Future Meeting Schedule

Dr. Passamani asked Pam Barclay to advise the Subcommittee of the schedule of future meetings. She stated that dates were not yet finalized, but plans were underway to schedule a Subcommittee on Long Term Issues meeting in November and December. And, if necessary, a meeting could be scheduled for sometime in the early part of 2003. Although it was originally anticipated that the Subcommittees would present their reports to the Steering Committee by January 2003, Drs. Donald E. Wilson and James Scheuer agree that more time is needed in order to provide fully developed reports. Therefore, the

Steering Committee will not be presenting the finalized report to the Commission until later in the next calendar year.

Regarding matters specific to the Subcommittee on Long Term Issues, it is hoped that Diane Becker, Sc.D., M.P.H., Professor of Medicine, Director, Johns Hopkins Center for Health Promotion, will be available to speak at the November meeting. Dr. Becker was scheduled to make a presentation at the July 25th meeting, but was unable to do so. Ms. Barclay also mentioned that it was time to start drafting portions of the Subcommittee Report. She pointed out that the information Dr. Ryan presented regarding heart disease in Maryland would be helpful to all of the subcommittees as well as the Steering Committee

Dr. Apson asked if Dr. Becker could talk about primary prevention in general, specifically what has been successful. Dr. Moran suggested keeping a "side list" of items that do not require funding, such as the AED program. This list could be provided to the Commissioners along with the items that required funding. He also asked if the MHCC had a link with the Maryland Insurance Commission. Ms. Barbara McLean replied that there was regular communication between the two agencies.

Ms. Casals asked if Ms. Myers could obtain physician regulations. Ms. Myers advised that regulations were included in the back of the AED packet. Dr. Moran suggested that physicians should be informed of the time commitment that would be involved. Dr. Passamani agreed and said that in order to get physicians involved, it was necessary to drive out the unknown. Dr. Apson suggested that physicians be advised of their role, the risks that are involved, and the legal protection they would receive.

7. Other Business

There was no other business.

8. Adjournment

The meeting adjourned at 7:30 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care Subcommittee on Long Term Issues

November 20, 2002
Maryland Health Care Commission
4160 Patterson Avenue, Baltimore, Maryland 21215

Committee Members Present
Eugene R. Passamani, M.D., Chairman
Jane R. Apson, M.S.P.H., Ph.D.[9]
Donald H. Dembo, M.D.
Sheila Druck, R.N., BSN
Lisa Myers, R.N., M.S.
Kenneth Rempher, R.N.
John M. Ryan, M.D.
Cheryl VanKuren

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Valerie McRae

Committee Members Absent

Jerilyn Allen, Ph.D.
William Balke, M.D.
Irene Buadoo, M.D.
Patricia Casals
Stacey Fisher, M.D.
Aaron Kenigsberg, M.D.
Ruth Maiorana
George Moran, M.D.

1. Call to Order and Introductions

Eugene R. Passamani, M.D., Chairman of the Long Term Issues Subcommittee, called the meeting to order at 6:10 p.m.

2. Approval of Previous Minutes (October 17, 2002)

Dr. Passamani asked if anyone wanted to modify the minutes of the last Subcommittee meeting. Ms. Lisa Myers requested a change on Page 4 to reflect, "EMS will provide the training that will begin January 31, 2003." Dr. Jane Apson requested that the second paragraph on Page 2 be changed to read, "Dr. Jane Apson has a bias….." Hearing no other changes, Dr. Passamani entertained a motion to approve the minutes of the Subcommittee's October 17, 2002 meeting as amended. Donald H. Dembo, M.D.

[9] Via Telephone Conference Call

moved approval, Ms. Cheryl VanKuren seconded his motion, and the members voted to approve the minutes.

3. Overview and Background

Dr. Passamani asked Ms. Pamela Barclay, Executive Director, Health Resources, MHCC, to provide a preview of upcoming subcommittee meetings. Ms. Barclay reported that the Cardiac Surgery Data Workgroup of the Quality Measurement and Data Reporting Subcommittee would meet on Tuesday, November 26, 2002. It is expected that the Subcommittee members will finalize their recommendation on that date. The Quality Measurement and Data Reporting Subcommittee of the Advisory Committee on Outcome Assessment in Cardiovascular Care will meet on Wednesday, December 11, 2002. The Subcommittee on Long Term Issues is scheduled to meet again on December 12, 2002. The next meeting of the Steering Committee of the Advisory Committee on Outcome Assessment in Cardiovascular Care will be held on Tuesday, December 17, 2002. A tentative date of December 23, 2002 has been set for the next meeting of the Interventional Cardiology Subcommittee.

4. Presentation: Hospital Performance Evaluation Guide

Dr. Passamani asked Ms. Barbara McLean, Executive Director, MHCC, to provide the members of the Subcommittee with an overview of the Hospital Performance Evaluation Guide. A handout (attached) was provided to each member of the Subcommittee that described the history of the guide, as well as a tentative timeline for guide development in the future and the names of the members of the Report Card Steering Committee. Ms. McLean advised that CMS had designated Maryland as the lead state for developing a hospital performance guide as part of a pilot program for national reporting similar to the recent nursing home pilot project. She said it is Maryland's goal to use the report card to facilitate continuous quality improvement. Currently, MHCC reports on its own website descriptive measures comparing LOS, discharges, and readmission rates based on the HSCRC data set. Ms. McLean also described the various features of the website design. Thirty-six DRGs are represented on the guide and a minimum of 20 cases is required for inclusion. Data from District of Columbia hospitals has also been included in the most recent version of the guide to more accurately calculate readmissions. The next phase of the hospital performance evaluation guide will focus on two JCAHO measurement sets which are community acquired pneumonia and congestive heart failure. These are sets of measures indicating whether the appropriate process of care was followed. A future step will be to include an obstetrics module because patients tend to shop for this type of medical service.

Dr. Passamani noted that there are errors in medicine and patients and families need to have more access to information about them. Providers also need these data to emulate the good providers. The Subcommittee should support quality measurement because it will encourage quality improvement. Dr. Dembo said there is historically experience with a report card because the Attorney General previously issued information on costs. That report card, however, did not deal with all of the issues, such as what to do

about under-performers—to encourage improvement. He said that people are under the impression that under performing doctors will leave if errors are pointed out, but that does not actually happen. Although we have to be prepared for negative feelings regarding the report card approach, Dr. Dembo noted that it was important to recognize the positive aspects of reporting quality indicator data. Report cards can be issued internally for quality improvement and accountability or externally for consumers. It may be that some information is more appropriately kept private while more conservative measures are made public.

5. Review and Discussion of Subcommittee Report Outline and Preliminary Recommendations

Dr. Passamani then asked Ms. Barclay to describe the structure of the upcoming report that the Subcommittee is to present to the Steering Committee. Ms. Barclay reviewed a suggested Table of Contents and preliminary list of recommendations for discussion by subcommittee members. The preliminary Table of Contents consisted of four components: I) Introduction, II) Overview Regarding Heart Disease in Maryland, III) Focus Areas, and IV) the Subcommittee Recommendations. Section II would focus on data that was presented by Dr. Ryan and Jeanette Jenkins. Section III would organize the subcommittee's discussions to include four principal areas, including Cardiovascular Health Status, Access to Care, Health Systems Organization and Research Agenda.

Dr. Passamani asked for comments from the Subcommittee members. Dr. Dembo stated process improvement is a moving target, but we can identify current problems and prioritize the issues that need to be addressed. He was not sure whether the Subcommittee should select one topic because there are a number of issues that need to be considered. He said enough is still not being done regarding secondary prevention and mentioned that the community at large needed to be educated regarding resuscitation. The Subcommittee should rank the prevention topics by importance, determine what we can and cannot do, and look to partner with those who can help us.

Mr. Kenneth Rempher stated that diabetes should be included in the subcommittee analysis and recommendations. Dr. Passamani agreed and said that diabetes tied into the early detection of sub-clinical coronary artery disease that Diane Bild, M.D. discussed during a previous Subcommittee meeting. He said it is difficult to talk healthy people into getting help. With better diagnostic devices and with the application of the burgeoning area of genetics, people will know their risk and that will help. Dr. Dembo said we need to get to it before heart failure occurs.

Dr. Apson identified three topics for subcommittee consideration: 1) access to care in rural vs. urban areas of the state; 2) approaches for containing costs for pharmaceutical drugs as an access issue; and 3) health status vs. secondary and tertiary level approaches. She noted that while resuscitation should be considered under tertiary approaches, diabetes control would be a primary prevention approach.

Dr. Passamani noted the epidemic of obesity in Maryland. He asked Ms. Barclay if the Subcommittee had access to obesity rates. Ms. Barclay replied that the Commission and Healthy People 2010 Project had data on the subject of obesity. Dr. Passamani suggested including that type of data in the overview section of the subcommittee's report. Ms. VanKuren stated that cost was a barrier to the program that should be under access to care. She said hypertension was another important area to consider in developing the subcommittee's recommendations.

Referring to the document containing draft subcommittee recommendations, Mr. Rempher asked if the suggestion to establish an annual award referred to a hospital program or community program. Ms. Barclay replied that the recommendation could refer to both. She noted that the subcommittee discussions had highlighted the good work being done by existing programs and the need to promote those programs and public awareness. Dr. Passamani commented that the American Heart Association would be a logical partner for this activity. Mr. Rempher said the subcommittee's recommendations should address the metabolic syndrome. Dr. Passamani stated there is a need to recognize and disseminate information about new risk factors for cardiovascular disease in general.

Mr. Rempher suggested that diabetes should be included under primary and secondary prevention. Ms. Sheila Druck said other risk factors such as smoking should also be added to the discussion. Dr. Dembo stated that issue of access to care by African Americans merited further study by the subcommittee. He noted that Med-Chi and the Monumental City Medical Society are collaborating on an effort to examine issues related to access to care by minorities.

Ms. Myers said all first responders should have automated external defibrillators (AEDs). Dr. Passamani said we need what is currently available and determine our goal with respect to increasing access to this technology. Ms. Myers said the American Heart Association (AHA) should be a partner with respect to the recommendation to increase use of AEDs in Maryland. Ms. Barclay asked about the potential use of home defibrillators recently approved by the Food and Drug Administration. Several subcommittee members suggested that a project to further evaluate the use of home defibrillators should be explored.

Ms. VanKuren suggested an addendum to recommendation to include community cardiac rehabilitation programs. Dr. Passamani noted the importance of cardiac rehabilitation and the fact that frequently the service is not utilized to its full potential. Ms. VanKuren pointed out that the barriers to cardiac rehabilitation programs, such as insurance and transportation, frequently limit utilization. She also noted the knowledge is frequently not enough because you have to get people to change their behavior with exercise, diet/nutrition, and behavior modification. The focus should be to educate people today in order to promote long-term prevention. Awareness has to come from making changes today.

Dr. Ryan stated that the more narrow the focus, the better chance of accomplishment, He suggested starting with hypertension and, if we get it right, we can add other risk factors. Dr. Ryan mentioned that Med Chi and the State Advisory Council on Heart Disease and Stroke should be included has partners. Dr. Passamani asked if stroke should be included. Dr. Dembo agreed that consideration should be given to including stroke in the subcommittee's recommendations.

Dr. Apson said tobacco efforts are important. She said the pharmaceutical issue is just as important because it is important to encourage the use of less expensive medications. Dr. Dembo agreed with Dr. Apson and said patients with diabetes, and patients with hypertension, do not always receive treatment because of the prohibitive cost of drugs.

Subcommittee members also suggested that Recommendation 1 be reworded to state "….of the importance of *controlling* high blood pressure" rather than "of the importance of *treating* high blood pressure." Recommendation 3 should be changed to read "Increase the use of *the number of persons with access to* external defibrillators to treat sudden, out-of-hospital cardiac arrest."

Dr. Passamani asked staff to revise the recommendations based on the subcommittee discussion.

6. Other Business

There was no other business discussed by the subcommittee.

7. Adjournment

The meeting adjourned at 7:20 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care
Subcommittee on Inter-Hospital Transport

August 22, 2002
Conference Room 108-109, Metro Executive Building, 4201 Patterson Avenue, Baltimore, Maryland 21215

Subcommittee Members Present

Jeffrey D. Jones, M.D., Chairman
Valerie Allen, R.N.
Andy Armetta
Cheryl Y. Bowen, M.S., M.A., R.N.
Patricia Casals
Lucy A. Ferko, R.N.
Thom Mayer, M.D.
Henry Meilman, M.D.
Stephen Pollock, M.D.
Ed Rupert
Todd Walker

Commission Staff Present

Barbara G. McLean
Pamela W. Barclay
Dolores Sands
Bridget Glazebrook
Susan Panek
Debbie Rajca
Colleen Lates

Subcommittee Members Absent

Jamie Brown, M.D.
Carole Woehlke, R.N.

Members of the Public Present

Angelyn B. Estwick, Master of Public Health Candidate, George Washington University
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

Jeffrey D. Jones, M.D., Chairman of the Inter-Hospital Transport Subcommittee, called the meeting to order at 6:10 p.m. Members of the Inter-Hospital Transport Subcommittee and Maryland Health Care Commission staff introduced themselves.

2. Overview and Background

Dr. Jones suggested that Ms. McLean provide an overview of the Commission. Ms. McLean thanked the subcommittee members for taking time from their busy professional and personal lives to participate in generating discussions relating to inter-hospital transport issues. Then Ms. McLean provided a brief overview and description of the activities and programs of the Commission. Ms. McLean also stated that the four

Subcommittees (Data Reporting, Interventional Cardiology, Long Term Issues, and Inter-Hospital Transport) would discuss ideas for future direction and relay their proposals to the Steering Committee for consideration.

3. Review and Discussion of the Subcommittee Charge, Structure, and Timetable

Dr. Jones asked if all of the subcommittee members had an opportunity to read the issues outlined by the Steering Committee concerning inter-hospital transport. Specifically, Dr. Jones reviewed the five questions that were listed:

1. Are there highly efficient systems in place in other states or countries that provide a model for Maryland? What are the components of the optimal inter-hospital transport system for cardiac patients? What specially trained staff is required to support the transport of emergency cardiac patients?

2. How should an inter-hospital transport system be organized and funded?

3. Should standard protocols be developed to guide the transport of emergency cardiac patients between hospitals? Who should develop them?

4. What standard data elements should be collected on inter-hospital transports for cardiac patients to benchmark current system performance and establish improvement goals? Who should collect the data?

5. Who should lead an effort to develop an improved statewide inter-hospital transport system?

Stephen Pollock, M.D. asked if there were any other state systems that utilized a cardiac inter-hospital transport system. He stated that he was not aware of any. Dr. Pollock said he was affiliated with 40 cardiology groups throughout the United States and he could contact them to determine if such a system was available.

According to Dr. Pollock, St. Joseph Hospital Center, Sinai Hospital of Baltimore, and Union Memorial Hospital recognize that development of an inter-hospital transport system is important. Consequently, the three hospitals are working together to create such a system for cardiac patients. Dr. Pollock then provided an overview of the system. He said that currently in Baltimore City, it takes approximately two to four hours to treat a cardiac patient from start to finish. The three hospitals expect to reduce this time to less than 90 minutes. They have already created some protocols and plan to create a system that is similar to the one of Maryland Institute for Emergency Medical Services Systems (MIEMSS). Patients will be taken to a particular hospital on a specific day of the week. A critical care team will track the patient from the beginning and document patient outcomes.

Dr. Pollock mentioned he will be meeting with some other area hospitals regarding implementing a cardiac inter-hospital transport system on a larger scale. These hospitals include the Greater Baltimore Medical Center, Carroll County General

Hospital, North Arundel Hospital, Mercy Medical Center, Good Samaritan Hospital and Upper Chesapeake Medical Center. It was also mentioned that Washington County Hospital and Upper Chesapeake Medical Center have helicopter pads on the grounds that allow for STAT helicopter transport of patients as needed. These transports involve one call from cardiology and one to the interventional team.

Ms. Ferko said some data is already available, such as dispatch time, arrival time, and ending time. She also stated that St. Joseph Medical Center did not have a helipad at the present time. Additionally, Ms. Ferko commented that St. Joseph Medical Center had not encountered any billing problems regarding transport.

Dr. Pollock said that he believes 40 to 50 patients will be served by the three-facility cardiac inter-hospital transport system during the first three months of implementation. He believes the system will be found viable and plans to go public with the idea after data has been collected and reviewed. He stated that the initial thought was to go through MIEMSS, but it was believed if statewide management was implemented, an enormous amount of money would be spent and there would still be an insufficient number of ambulances. According to Dr. Pollock, private funding might be more feasible. Ms. McLean asked if insurers had been brought into the three-hospital transport system. Ms. Ferko responded that there was an agreement with the three hospitals.

Thom Mayer, M.D. stated that Medicare pays for the nearest hospital that is "capable" of caring for patients. He stressed that transport reimbursement could be denied if a patient does not go to the nearest capable hospital. Dr. Pollock said that if proper protocol were followed, a patient would be taken to the nearest hospital. However, he added that this was not how the current state health system works.

Dr. Jones commented that it is difficult to find nurses after hours and during weekend hours. Ms. Ferko agreed there was indeed a nursing shortage. She added that Maryland paramedics were treated differently than paramedics in other states. Ms. Ferko said that in Maryland, a nurse was required to accompany a paramedic during transport for certain types of patients. However, this was not necessarily true in other states.

Mr. Todd Walker stated that having a nurse on board an ambulance during an inter-hospital transport works well. He said that although his office is located in Ohio, he deals with other states on the Eastern portion of the country and is aware of their procedures. He agreed that Maryland is the only state that requires a nurse to accompany a paramedic.

Ms. Bowen advised that paramedics in Maryland operate under certain protocols that sometimes require nurses. Ms. Ferko asked why paramedics could handle the responsibility of transports in other states, but not in Maryland. Ms. Bowen responded that in a few states, only paramedics were required. According to Dr. Mayer, Virginia resembled Maryland because a nurse is required during transport. Patricia Casals, R.N. noted that Peninsula Regional Hospital employs a registered nurse for transports. Ms. Ferko asked if there was a possibility of expanding the role of paramedics with support

and training. Ms. Bowen advised that it would take 18 months to review and adopt protocols.

Dr. Pollock said the facilities involved in the three-hospital transport would gather information based on three months worth of data and answer questions to determine if the cardiac inter-hospital transport was a success.

Henry Meilman, M.D. commented that C-PORT arose, as least in part, out of frustration. He said a person could dial 911 and have an ambulance unit available within 12 minutes. Unfortunately, this is not the case with transports between hospitals. Dr. Meilman stated his belief that if someone in Maryland has a myocardial infarction, he or she should have access to first class care. He said the subcommittee's responsibility is to develop a mechanism to accomplish this important goal.

Mr. Walker commented that the volume is there, but reimbursement is not. He said there is no differential between nurses and paramedics. There should be something included for the cost of the nurses and the private sector will fill the void.

Dr. Pollock said the subcommittee should try to get all hospitals to agree to certain standards for inter-hospital transport of cardiac patients and Dr. Meilman suggested that perhaps the Commission could adopt policies in the State Health Plan to implement inter-hospital transport recommendations.

Dr. Meilman commented there is a perception that a nurse has to accompany a patient during transport. Ms. Bowen advised that it actually revolves around how sick the patient is. She said MedStar and other helicopters always staff with a nurse.

Dr. Mayer noted the problems with having sufficient nurses to support inter-hospital transport. He also pointed out that while some nurses are comfortable during transports, other nurses are concerned about malpractice suits and vehicular accidents.

Ms. Barclay referred to the list of questions that had been distributed to the subcommittee members. She referred to Question 1, "Are there highly efficient systems in place in other states or countries which provide a model for Maryland?

Dr. Pollock replied that he would work to get an answer to that question. He said he would send an e-mail to his contact in the cardiology community throughout the country to determine if such systems existed. Dr. Mayer said that in Western states, there are some places where they are sending all patients. He stated he would obtain the names of these facilities.

Mr. Rupert said the Mayo Clinic operates a transport system. Mr. Rupert also stated that a system does exist today and, with some "tweaking," it could improve. He stated that treatment times were already available and that transport works well with remote areas. He suggested that consideration be given to expanding the scope of paramedics. This would allow for more availability of transport vehicles. According to

Mr. Rupert, the Medicaid system operates based on a county contract with only limited reimbursement for helicopter transports.

Ms. Barclay said that it would be helpful to get information on the volume and characteristics of inter-hospital transports involving cardiac patients. She suggested that reimbursement and scope of practice be added to the subcommittee issues list. Then she asked if there were any issues that should be removed.

Dr. Jones asked if Maryland could achieve a statewide system. Dr. Pollock stated there is the issue of private versus state. He suggested that a standard system to transport patients was needed, along with recommendations for reimbursement. Dr. Meilman commented that a patient suffering a heart attack in Oakland (Garrett County), and at Bon Secours Hospital (Baltimore City) should be treated the same manner. Dr. Pollock agreed this was true, especially if there were only a limited number of centers.

Ms. McLean stated that private versus public was good question to consider. She agreed that the subcommittee should also think about the area of reimbursement. Mr. Rupert said that if there was appropriate funding, there would be enough competition to make the transport program successful.

4. Presentation: Maryland Neonatal Intensive Care Transport System

Ms. Barclay commented that this would be a good transition to discuss neonatal intensive care units (NICUs) regarding the transport of critically ill infants. She asked Ms. Cheryl Bowen to provide background information for the subcommittee regarding the neonatal transport system in Maryland.

Ms. Bowen noted that neonatal transport actually began in 1980 when it was recognized that outcomes were improved when babies could be transported to the proper facility. The Maryland State Police actually started the transport program and then the local emergency medical service departments became involved. This was sufficient when there were only a few transports, but then transports increased, and care also became more sophisticated.

Over time, the program was centralized at MIEMSS from two university centers, the University of Maryland Medical System and the Johns Hopkins Medical System. By the mid-1990s, legislators recommended that MIEMSS get out of the transport business. The system is working efficiently and, currently, there is always a primary nurse and backup nurse. Nurses or nurse practitioners are hospital employees. The contact is with Rural Metro and calls come to a central number and are directed to the scheduled rotated hospital.

Dr. Pollock commented that the transport system in which he is involved is similar to the University of Maryland Medical System and the Johns Hopkins Medical System. However, the cardiac transport project involves three hospitals instead of two. Mr. Rupert suggested that a hospital-based consortium could be the answer. He stated

that Frederick, LaPlata, and Easton, for example, are all within a 20-minute transport time.

Dr. Pollock stated that direct angioplasty would be a major type of treatment in the future. However, he said there might not be enough ambulances to handle the volume of these patients. Mr. Rupert commented that the data should be available regarding the likely volume of patients. Ms. Barclay advised that the Commission had another subcommittee that would be discussing primary and elective angioplasty.

5. Future Meeting Schedule

Ms. Barclay advised that that the first Interventional Cardiology Subcommittee meeting was scheduled for September 4, 2002. She said that the members of the Inter-Hospital Subcommittee would be getting the materials related to that meeting. Ms. Barclay also advised that there were three tentative dates for future Inter-Hospital Transportation subcommittee meetings. These dates were September 18th, September 30th, and October 24th. After some discussion, it was decided that the subcommittee would meet on September 30th, in person. For the October meeting, it was agreed that the Subcommittee would consider teleconferencing in order to accommodate the members who had to travel a great distance.

Mr. Rupert asked what minimum data sets would be useful such as times and outcome. Ms. Barclay said that data should include, time of arrival at interventional center, time of pickup, time to complete the procedure, and the outcome.

6. Other Business

There was no other business discussed by the Subcommittee.

7. Adjournment

The meeting adjourned at 7:30 p.m.

Summary of the Meeting of the Advisory Committee on Outcome Assessment in Cardiovascular Care
Subcommittee on Inter-Hospital Transport

September 30, 2002
Conference Room 108-109, Metro Executive Building, 4201 Patterson Avenue, Baltimore, Maryland 21215

Subcommittee Members Present
Jeffrey D. Jones, M.D., Chairman
Valerie Allen, R.N.
Andy Armetta
Cheryl Y. Bowen, M.S., M.A., R.N.
Jamie Brown, M.D.
Patricia Casals, R.N.
Carol Curran, R.N.
Lucy A. Ferko, R.N.
Michael Franklin
Eric Lieberman, M.D.
Henry Meilman, M.D.
Stephen Pollock, M.D.
Ed Rupert
Todd Walker

Subcommittee Members Absent

Thom Mayer, M.D.
Carole Woehlke, R.N.

Commission Staff Present

Pamela W. Barclay
Bridget Glazebrook
Colleen Lates
Susan Panek
Dolores Sands

Members of the Public Present

Guy Barber, STAT MedEvac
Sean P. Flanagan, Director, Government Relations, St. Joseph Medical Center
Martha Nathanson, Vice President, Government Relations, LifeBridge Health
Vanessa Purnell, MedStar Health

1. Call to Order and Introductions

Jeffrey D. Jones, M.D., Chairman of the Inter-Hospital Transport Subcommittee, called the meeting to order at 6:05 p.m., and asked the members of the Subcommittee and Commission staff to re-introduce themselves.

2. Approval of the Previous Minutes (August 22, 2002)

Dr. Jones asked for a motion to approve the minutes of the Subcommittee's August 22, 2002 meeting. Dr. Pollack moved approval, Ms. Casals seconded his motion, and the members voted to approve the minutes as presented.

3. Presentations: Inter-Hospital Transport Systems

Four Subcommittee members gave brief presentations on the systems for inter-hospital transport in which each is involved.

Patricia Casals, R.N., Clinical Nurse Manager for Interventional Cardiology at Peninsula Regional Medical Center (PRMC) in Salisbury, described a transport protocol developed by agreement between PRMC, Atlantic General Hospital (AGH) in Berlin, and the Town of Ocean City, that is used to determine where the local EMS teams are to transport an AMI case in the field. This protocol directs that if a patient is contraindicated for thrombolytics, the patient is taken directly to PRMC, which has both interventional cardiology and cardiac surgery programs. If thrombolytics are not contraindicated for that patient, then the EMS team transports that AMI patient to AGH, where its Emergency Department physicians decide whether or not to administer thrombolytic drugs. This patient is likely still to be transported to PRMC, if AGH physicians have administered thrombolytics and determined that angioplasty or other medical intervention is necessary.

Dr. Pollock questioned the reasoning behind this protocol given the medical literature and accepted clinical practice, and asked whether the Subcommittee could raise its concerns about the protocol to PRMC and AGH. Dr. Jones asked how long the AGH physicians wait before further transfer of AMI patients, when indicated; Ms. Casals referred the Subcommittee to the MedStar transport report, since that system is often called to transport patients to PRMC by air. Dr. Pollock observed that this data is mixed, and includes more than AMI patients. Ms. Casals responded that the three parties to this protocol, the two hospitals and Ocean City government, are still working on ways to refine collection and analysis of information, to separate out non-AMI transports and Delaware patients, noting that the system was still "a work in progress."

Ed Rupert, Director or Air and Ground Transport for the MedStar program at Washington Hospital Center, presented information on that system's existing coverage by air ambulance, which for Maryland includes three MedStar and one of the two regional STAT helicopters. These data summarized the experience of both MedStar and STAT transports for FY 2002. As with all reports of transport times in cardiac cases, when the "clock" starts -- from the onset of chest pain, from the first call to 911, from the receiving ED to the available inter-hospital transport system – to the defined point of measurement (to the lab, the table, to balloon) must be consistent, in order for valid comparisons to be made. Dr. Jones observed that another variable contributing to the apples-to-oranges nature of this data, when it is even available, is the time it may take to determine if a patient receiving thrombolytic therapy has experienced successful reperfusion.

Ms. Bowen asked if MedStar, and other transport systems, track such events as the times a helicopter is not available; Mr. Rupert replied that his organization does track what it calls "missed flights," which can occur when weather precludes flying, when helicopters are undergoing routine maintenance, and when all helicopters are occupied on calls.

Todd Walker, President for the Mid-Atlantic Region of the Rural Metro Corporation, introduced his presentation with a handout summarizing the resources his organization has available in the region, and the average times of calls by priority (with priority 1 defined as dire need, 2 as a call needing transport within an hour or two, 3 as

need for transport within 24 hours, and 4 as able to be scheduled the next day.) The times for priority one calls Mr. Walker presented – ranging from a minimum of 33 minutes to a maximum of 1:46, with an average of 1:01 hours -- his organization defines as the total time from dispatch to destination, including pickup at the scene, and transport time. Rural-Metro does not measure "time to table," which occurs once a call is at the hospital, but is establishing mechanisms to collect that time as well. Mr. Walker noted that 68% of Rural-Metro's transports in July 2002 were cardiac-related, and that this percentage of cardiac calls to all others remains fairly consistent throughout the year.

Dr. Lieberman observed that Holy Cross encounters a situation not consistently reflected in transport time data collection and reporting: if one of the three ambulance services his hospital uses will respond that an ambulance is not available because no nurse is available to staff the run, this may not be reflected as a lost call. Mr. Walker responded that Rural-Metro has similar issues, since it tracks the lost calls themselves, not why no transport could be arranged.

Stephen Pollock, M.D., of Mid-Atlantic Cardiovascular Associates, P.A., and Lucy A. Ferko, R.N., Administrative Director of Cardiac Services at St. Joseph Medical Center, presented an update on the development by the three Baltimore area community hospitals with cardiac surgery programs -- St. Joseph Medical Center, Sinai Hospital of Baltimore, and Union Memorial Hospital -- of a cooperative venture in inter-hospital transport, called Team Critical Care ("TCC"). Dr. Pollock first described this venture at the Subcommittee's August 22, 2002 meeting, noting that the three hospitals were working together to create an inter-hospital transport system for cardiac patients, in an attempt to minimize both the administrative and clinical delays patients have historically experienced in transfers between hospitals, once a decision on treatment has been reached.

Dr. Pollock described the process of going to the three participating hospitals' own emergency departments to explain the TCC protocols, where, predictably, physicians and other staff raised many questions about how the system would work, and under what, and what level, of authority. He characterized the overall operational goals of Team Critical Care as having an ambulance, and a nurse, to the transferring hospital within 30 minutes of a call, and addressing the "time on site" problems by keeping its own paperwork simple, and urging the transferring ED to minimize the use of drips and other measures that may add time to transfers. In addition, the hospital participants in Team Critical Care have agreed that cardiac catheterization labs in their institutions will be ready in one hour for any patient transferred there by TCC.

Dr. Pollock and other representatives of TCC have begun visiting other metropolitan area hospitals, to explain the transport system and encourage the emergency department physicians and cardiologists to participate, with the overall goal of improving the treatment of AMIs in the service area. To date, he has talked with staff at Greater Baltimore Medical Center, Upper Chesapeake Medical Center, and the Mid Atlantic Cardiovascular Associates staff at St. Joseph's.

Dr. Pollock emphasized that data collected in the course of the next several months should help the hospitals – and this Subcommittee – evaluate the effectiveness of this collaborative model for inter-hospital transport of cardiac patients in reducing the time from "call to table," now about an hour and twenty minutes in the Baltimore area. These data and the conclusions drawn from the first several months' experience of Team Critical Care should also inform the Subcommittee's further discussions on what kind of a model it will recommend to the Advisory Committee – a recommendation that must be integrated with those of the other Subcommittees, particularly the Interventional Cardiology Subcommittee. The Team Critical Care approach to inter-hospital transport is based upon the assumption that primary angioplasty is, in most cases, the most appropriate intervention for AMI, and, Dr. Pollock observed, physicians continue to give thrombolytics because they expect to encounter delays in transport.

The Subcommittee discussed the likelihood that the Team Critical Care approach could represent a workable solution to the ongoing problems with inter-hospital transport, as well as a means to continue improving call-to-table times and the overall standard of AMI care. In response to questions, Ms. Bowen noted that the EMS system should not be looked to as a resource for inter-hospital transport. In response to Dr. Meilman's comment that the Subcommittee should still consider whether "stat transport" should be a part of the inter-hospital transport system, Dr. Pollock observed that, after six months or so of TCC's experience – its number of lost calls as compared to successful transports, and what that may suggest about the need for emergency transfers – the Subcommittee might yet recommend a "mandate" for an EMS role in this area.

Dr. Pollock suggested that the Subcommittee could encourage the further standardization of the data collected on inter-hospital transport, and the inclusion of data on the measures taken at the scene that may prolong transfer time, since as starting intravenous drips. Several Subcommittee members noted ways to minimize transition time, even if a patient is on an IV drip.

Ms. Barclay, observing that TCC represented a Baltimore metropolitan are approach to the transport issue, asked about the Washington metropolitan area's view of these issues. Dr. Lieberman responded that the dynamics are quite different, with one dominant cardiac surgery program at Washington Hospital Center, and most transports, consequently, made by MedStar. While there seems to be a high degree of satisfaction with that situation, Dr. Lieberman agreed that the TCC model has promise as a prototype, in part because it seeks to simplify the paperwork and clinical transitions involved in patient transfers. Mr. Rupert observed that the Washington region could benefit from the TCC approach, if its hospitals would work together. Mr. Franklin also noted that, since many of the Washington metro area hospitals participate in the C-PORT project and therefore perform direct angioplasty, the inter-hospital transport issues are "not so urgent."

Ms. Barclay asked that the Subcommittee members review the TCC packet, and forward any suggestions about the data collection; Dr. Pollock suggested that the Subcommittee might write to all interventional cardiologists and their hospitals, to be sure that all of the appropriate time frames are included in any data collection effort.

Dr. Jones then asked Guy Barber from STAT MedEvac to describe his group's development, and its growth as a regional resource for inter-hospital transports. STAT MedEvac began as a consortium between hospitals in Western Pennsylvania, spread to the central part of that state, and came into Maryland at the request of Johns Hopkins Hospital in March 2001. The organization makes between 60 and 70 flights in Maryland each month, also serving St. Joseph's and Sinai through non-binding contracts. Mr. Barber characterized an important reason for STAT's success as "[the hospitals'] frustration with what used to be in place." He described the "One Call" system, which features a guarantee to call other services if STAT MedEvac cannot respond, and to arrange an alternative. STAT flies with a flight nurse and a technician, with the aim of "getting in and out, and doing what's needed in the helicopter." He noted that the company will soon have a helicopter based in Southern Pennsylvania, in response to many requests for transport from Carroll and Washington Counties.

Dr. Jones led the Subcommittee in more discussion about data collection issues, and the importance of standard definitions of elements and variables to be collected. Dr. Pollock said that he would ask the University of Maryland Medical Center and Johns Hopkins, each of which has its own transport system, to share that data with the Subcommittee. Dr. Jones suggested that members should bring any ideas on the data collection issues to the next Subcommittee meeting. Dr. Meilman wondered if the Subcommittee should set a quantifiable goal for any inter-hospital transport system developed in response to the work of the Subcommittee, expressed in terms of the availability of transports or treatment, or measured in transport time, such as "angioplasty for 90% of the population within 90 minutes." Dr. Jones replied that he did not yet perceive a consensus around what such a goal should be, and observed that regional goals might prove more workable.

Ms. Barclay said that staff would compile any suggestions related to data collection received via e-mail, and also begin putting together a document to describe the systems in place, the remaining problems related to inter-hospital transport, and potential solutions, based on the Subcommittee's discussion. She again reminded the members that the work of the other Subcommittees, particularly of the Interventional Cardiology Subcommittee, would come to the Advisory Committee with those of this Subcommittee, in developing the larger body's final recommendations to the Commission.

4. Other Business

Ms. Barclay gave a brief update on the activities of the other Subcommittees, and the Advisory Committee.

5. Adjournment

The meeting adjourned at 7:45 p.m.

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